Enanta Pharmaceuticals Reports Financial Results for its Fiscal Second Quarter Ended March 31, 2025

May 12, 2025

- *Met Target Enrollment for RSVHR, a Phase 2 Study of Zelicapavir in High-Risk Adults Infected with Respiratory Syncytial Virus (RSV); On Track to Report Topline Data in Late 3Q 2025*
- *STAT6 Program Progressing with Plans to Select a Development Candidate in 2H 2025*
- *IND Enabling Studies of KIT Inhibitor EPS-1421 Ongoing*
- *Cash and Marketable Securities Totaling $193.4 Million at March 31, 2025, Further Strengthened by a $33.8 Million Federal Income Tax Refund Received in April 2025*

WATERTOWN, Mass.--(BUSINESS WIRE)--May 12, 2025-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for viral infections and immunological diseases, today reported financial results for its fiscal second quarter ended March 31, 2025.

“Throughout the fiscal second quarter, Enanta remained squarely focused on executing across our virology and immunology pipeline. We are thrilled to have enrolled our target of 180 patients in RSVHR, a Phase 2 study of zelicapavir in high-risk adults infected with RSV, and plan to complete enrollment in late May to capture the remainder of the current Northern Hemisphere RSV season. We remain on track to report topline data late next quarter. With two differentiated mechanisms of action, N- and L-protein inhibition, Enanta has the most comprehensive RSV antiviral portfolio in development, and we will evaluate potential partnership opportunities to bring these therapeutics to patients,” said Jay. R. Luly, Ph.D., President and Chief Executive Officer at Enanta Pharmaceuticals.

Dr. Luly continued, “We are also pleased with the progress we have made in advancing our immunology programs that target key drivers of type 2 inflammation. We expect to select a lead development candidate for our oral STAT6 inhibitor program in the second half of this year, with an initial indication in atopic dermatitis and future expansion opportunities in asthma and other diseases. Additionally, we are continuing to advance EPS-1421, the lead development candidate in our KIT inhibitor program, with the goal of developing a best-in-disease, oral treatment for chronic spontaneous urticaria and other mast cell driven diseases. We look forward to continuing to expand our immunology portfolio with the announcement of a third program this year. With a strong cash position and a disciplined approach to capital allocation, we are well-suited to execute across our pipeline of oral therapeutics in development for virology and immunology indications.”

Fiscal Second Quarter Ended March 31, 2025 Financial Results

Total revenue for the three months ended March 31, 2025 was $14.9 million and consisted of royalty revenue from worldwide net sales of AbbVie’s hepatitis C virus (HCV) regimen MAVYRET®/MAVIRET® (glecaprevir/pibrentasvir), compared to $17.1 million for the three months ended March 31, 2024.

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 price, after which point 100% of the cash royalty payments will be retained by Enanta. Interest expense from the royalty sale was $1.7 million for the three months ended March 31, 2025, as compared to $2.6 million for the same period ended March 31, 2024.

Research and development expenses totaled $28.1 million for the three months ended March 31, 2025, compared to $35.6 million for the three months ended March 31, 2024. The decrease was primarily due to a decrease in expenses as a result of the timing of clinical trials in the Company’s RSV program.

General and administrative expenses totaled $11.4 million for the three months ended March 31, 2025, compared to $14.2 million for the three months ended March 31, 2024. The decrease was primarily due to a decrease in legal expenses related to the Company’s patent infringement lawsuit against Pfizer.

Interest and investment income, net, totaled $2.3 million for the three months ended March 31, 2025, compared to $3.8 million for the three months ended March 31, 2024. The decrease was due to lower cash and investment balances year-over-year.

Enanta recorded an income tax benefit of $1.3 million for the three months ended March 31, 2025 primarily due to an additional federal income tax refund of $0.9 million. Enanta recorded an income tax benefit of $0.4 million for the three months ended March 31, 2024 related to interest earned on the federal income tax refund. The federal income tax refund of $33.8 million, including interest, was received in April 2025.

Net loss for the three months ended March 31, 2025 was $22.6 million, or a loss of $1.06 per diluted common share, compared to a net loss of $31.2 million, or a loss of $1.47 per diluted common share, for the corresponding period in 2024.

Enanta’s cash, cash equivalents and short-term marketable securities totaled $193.4 million at March 31, 2025. Enanta expects that its current cash, cash equivalents and marketable securities, as well as its retained portion of future royalty revenue, together with a $33.8 million federal income tax refund received in April 2025, will be sufficient to meet the anticipated cash requirements of its existing business and development programs into fiscal

2028.

Virology

- Enanta's virology pipeline is focused on developing oral antiviral treatments for serious infections, including multiple clinical-stage programs for the treatment of RSV. Enanta has the leading RSV therapeutic portfolio, consisting of zelicapavir and EDP-323, both in Phase 2 development for RSV infection. The Company will evaluate potential partnership opportunities to further develop its RSV assets.
    - Zelicapavir, a potent, oral N-protein inhibitor, which has Fast Track designation from the U.S. Food and Drug Administration, is currently being evaluated in RSVHR, a Phase 2b, randomized, double-blind, placebo-controlled study in adults with RSV infection who are at high-risk of complications. This includes patients over age 65 years and/or those with congestive heart failure, chronic obstructive pulmonary disease or asthma. Target enrollment of 180 patients in RSVHR has been met. Enanta is continuing enrollment through late May to capture the remainder of the Northern Hemisphere RSV season. The Company will complete enrollment this month, with topline data expected late next quarter. Zelicapavir previously demonstrated positive data in a Phase 2 human challenge study and in a Phase 2 study of pediatric patients.
    - Enanta's second RSV asset, EDP-323, is a potent, oral L-protein inhibitor, which also has Fast Track designation. In a human challenge study, EDP-323 achieved highly statistically significant reductions in both viral load and clinical symptoms compared to placebo, as well as a favorable safety and tolerability profile. EDP-323 can be used alone or in combination with other agents, such as zelicapavir, to potentially broaden the treatment window or addressable patient populations.
    - In March, Enanta presented data from its RSV portfolio at the 13th International RSV Symposium (RSV2025). Results from a Phase 2 human challenge study of EDP-323 were highlighted in an oral presentation, while data from the Phase 2 study of zelicapavir in pediatric patients were presented in a late breaker poster. An additional poster highlighted distinctions among fusion, N-, and L-protein inhibitors with respect to preclinical antiviral effect and resistance profiles, while a final poster detailed PK and PK/PD results from the EDP-323 Phase 2 human challenge study. Copies of these presentations can be found on the Company's website.

Immunology

- Enanta's immunology pipeline is focused on designing and developing highly potent and selective oral inhibitors for the treatment of inflammatory diseases, by targeting key drivers of the type 2 immune response.
    - KIT inhibitors
        - Enanta's lead development candidate, EPS-1421, is a novel, potent and selective oral inhibitor of KIT, a receptor tyrosine kinase and central regulator of mast cell development and activation. The Company is currently conducting scale-up activities and IND enabling studies.
    - STAT6 Inhibitors
        - Enanta's second immunology program is targeting STAT6, the transcription factor responsible for IL-4/IL-13 signaling, which drives a type 2 dominant phenotype and downstream inflammation. Type 2 dysregulation is responsible for multiple allergic and autoimmune diseases.
        - Enanta's prototype oral STAT6 inhibitors exhibit nanomolar inhibition in biochemical and cellular assays, with good intrinsic permeability and oral bioavailability. In addition, inhibition of IL-4 induced phosphorylation of STAT6 in human peripheral blood mononuclear cells (hPBMC) and prevention of TARC production, a STAT6 biomarker of type 2 inflammation, have been observed. Further, the STAT6 prototypes are highly selective, with no inhibition of other STATs in hPBMCs and more than 1000-fold biochemical selectivity over other STATs, demonstrating significantly more selectivity than JAK inhibitors. In a mouse model, a prototype oral inhibitor resulted in rapid and complete inhibition of IL-4 induced phosphorylated STAT6 after a single dose, demonstrating *in vivo* target engagement.
        - The Company plans to select a STAT6 development candidate in the second half of 2025.
    - Enanta plans to expand its immunology pipeline with the introduction of a third program in 2025.

Corporate

- In April 2025, the Company received a $33.8 million federal income tax refund.
- On March 21, 2025, Enanta filed an opening brief with the United States Court of Appeals for the Federal Circuit. The original case was filed in the United States District Court for the District of Massachusetts on June 21, 2022, against Pfizer, Inc. seeking damages for infringement of U.S. Patent No. 11,358,953 (the '953 Patent) in the manufacture, use and sale of Pfizer's COVID-19 antiviral, Paxlovid™ (nirmatrelvir tablets; ritonavir tablets).
- Enanta plans to issue its fiscal third quarter financial results press release on August 11, 2025.

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 timeline and prospects for advancement of Enanta's clinical programs in RSV and its preclinical immunology programs, including its 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 ability to partner its RSV or other programs; 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, 2024, 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 March 31,		Six Months Ended March 31,	
	2025	**2024**	**2025**	**2024**
Revenue	$ 14,926	$ 17,054	$ 31,885	$ 35,057
Operating expenses				
Research and development	28,065	35,585	55,721	71,956
General and administrative	11,388	14,235	24,234	30,753
Total operating expenses	39,453	49,820	79,955	102,709
Loss from operations	(24,527)	(32,766)	(48,070)	(67,652)
Interest expense	(1,714)	(2,563)	(3,676)	(6,004)
Interest and investment income, net	2,292	3,809	5,091	8,107
Loss before income taxes	(23,949)	(31,520)	(46,655)	(65,549)
Income tax benefit	1,305	363	1,721	985
Net loss	$ (22,644)	$ (31,157)	$ (44,934)	$ (64,564)
Net loss per share				
Basic	$ (1.06)	$ (1.47)	$ (2.11)	$ (3.06)
Diluted	$ (1.06)	$ (1.47)	$ (2.11)	$ (3.06)
Weighted average common shares outstanding				
Basic	21,355	21,167	21,295	21,128
Diluted	21,355	21,167	21,295	21,128

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

	March 31, 2025	September 30, 2024
Assets		

Current assets		
Cash and cash equivalents	$ 60,213	$ 37,233
Short-term marketable securities	133,162	210,953
Accounts receivable	6,792	6,646
Prepaid expenses and other current assets	8,857	12,413
Income tax receivable	33,836	31,999
Short-term restricted cash	-	608
Total current assets	242,860	299,852
Property and equipment, net	37,572	32,688
Operating lease, right-of-use assets	39,103	40,658
Long-term restricted cash	3,360	3,360
Other long-term assets	98	94
Total assets	$ 322,993	$ 376,652
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 4,756	$ 8,002
Accrued expenses and other current liabilities	8,314	13,547
Liability related to the sale of future royalties	30,681	34,462
Operating lease liabilities	2,196	1,524
Total current liabilities	45,947	57,535
Liability related to the sale of future royalties, net of current portion	125,379	134,779
Operating lease liabilities, net of current portion	56,536	53,943
Series 1 nonconvertible preferred stock	1,350	1,350
Other long-term liabilities	243	231
Total liabilities	229,455	247,838
Total stockholders' equity	93,538	128,814
Total liabilities and stockholders' equity	$ 322,993	$ 376,652

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