Enanta Pharmaceuticals Reports Financial Results for its Fiscal Fourth Quarter and Year-Ended September 30, 2025

November 17, 2025

- *Announces EPS-3903, an Oral, Once-Daily STAT6 Inhibitor Development Candidate with Rapid, Continuous and Complete (>90%) In Vivo pSTAT6 Suppression and Efficacy Comparable to Dupilumab in Asthma and Atopic Dermatitis Disease Models*
- *Announces EDP-978, an Oral, Once-Daily KIT Inhibitor Clinical Candidate with Plans to File an Investigational New Drug Application in Q1 2026*
- *Reported Positive Topline Data for RSVHR, a Phase 2b Study of Zelicapavir in High-Risk Adults Infected with Respiratory Syncytial Virus (RSV)*
- *Strong Financial Position Ending Fiscal 2025 with $188.9 Million in Cash, Cash Equivalents and Marketable Securities; Further Strengthened by Gross Proceeds of $74.8 Million Upsized Public Offering in October 2025 and Continuing Retained Royalties, Expected to Fund Operations into Fiscal 2029*

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 17, 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 fourth quarter and year-ended September 30, 2025.

“This past quarter marked a pivotal period for Enanta, with significant progress across our virology and immunology programs, highlighted by positive topline data from the RSVHR study, our Phase 2b clinical trial in high-risk adults infected with RSV. These Phase 3-enabling results underscore zelicapavir’s ability to meaningfully reduce the duration of RSV symptoms and represent the first time an antiviral treatment demonstrated a clinically meaningful benefit in high-risk adult outpatients with RSV,” said Jay R. Luly, Ph.D., President and Chief Executive Officer at Enanta Pharmaceuticals. “In parallel, we reached an important milestone for our oral STAT6 program with the selection of EPS-3903 as our lead development candidate for the treatment of type 2 immune-driven diseases. This novel, potent and selective inhibitor has demonstrated rapid, continuous and complete pSTAT6 suppression of greater than 90%, and efficacy comparable to dupilumab in multiple asthma and atopic dermatitis disease mouse models after oral dosing. We look forward to filing an Investigational New Drug application for this program in the second half of 2026. Additionally, we have nominated EDP-978 as our oral, once-daily KIT inhibitor clinical candidate for the treatment of mast-cell driven diseases, with plans to file an IND in the first quarter of 2026. Taken together, this progress underscores our commitment to developing small molecule treatments for immunological diseases.”

Fiscal Fourth Quarter and Year-Ended September 30, 2025 Financial Results

Total revenue was $15.1 million for the three months ended September 30, 2025, which consisted of royalty revenue derived from worldwide net sales of AbbVie’s hepatitis C virus (HCV) regimen MAVYRET®/MAVIRET®, compared to $14.6 million for the three months ended September 30, 2024. The increase in the quarter is due to an increase in AbbVie’s sales of MAVYRET®/MAVIRET®. For the twelve months ended September 30, 2025, total revenue was $65.3 million compared to $67.6 million for the same period in 2024. The decrease in year-over-year revenue is due to a decline in AbbVie’s sales of MAVYRET®/MAVIRET® in the first nine months of fiscal 2025.

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 $2.4 million for the three months ended September 30, 2025 and $7.7 million for the twelve months ended September 30, 2025. This compares to interest expense of $2.6 million for the three months ended September 30, 2024 and $10.9 million for the twelve months ended September 30, 2024.

Research and development expenses were $23.8 million for the three months ended September 30, 2025, compared to $30.8 million for the three months ended September 30, 2024. For the twelve months ended September 30, 2025, research and development expenses were $106.7 million compared to $131.5 million for the same period in 2024. The decrease in the quarter and year-over-year research and development expenses is primarily due to a decrease in expenses as a result of the timing of clinical trials in Enanta’s RSV programs, partially offset by increased costs associated with the Company’s immunology programs.

General and administrative expenses totaled $9.7 million for the three months ended September 30, 2025, compared to $13.7 million for the three months ended September 30, 2024. For the twelve months ended September 30, 2025, general and administrative expenses were $43.9 million compared to $57.9 million in 2024. The decrease in the quarter and year-over-year general and administrative expenses is due to a decrease in legal expenses related to the Company’s patent infringement lawsuit against Pfizer and a decrease in stock-based compensation expenses.

Interest and investment income, net, totaled $2.1 million for the three months ended September 30, 2025, compared to $3.2 million for the three months ended September 30, 2024. For the twelve months ended September 30, 2025, interest and investment income, net, totaled $9.5 million compared to $14.8 million in 2024. The decrease in the quarter and year-over-year interest and investment income was primarily due to lower cash and lower income on the investment balances.

Enanta recorded an income tax expense of less than $0.1 million for the three months ended September 30, 2025, compared to an income tax benefit of $0.4 million for the three months ended September 30, 2024. Enanta recorded an income tax benefit of $1.7 million for each of the twelve-month periods ended September 30, 2024 and 2025. Enanta recorded interest earned on its federal income tax refund during fiscal 2024 and 2025 until the $33.8 million refund was received in April 2025.

Net loss for the three months ended September 30, 2025, was $18.7 million, or a loss of $0.87 per diluted common share, compared to a net loss of $28.8 million, or a loss of $1.36 per diluted common share, for the corresponding period in 2024. For the twelve months ended September 30, 2025, net loss was $81.9 million, or a loss of $3.84 per diluted common share, compared to a net loss of $116.0 million, or a loss of $5.48 per diluted common share for the corresponding period in 2024.

Enanta's cash, cash equivalents and marketable securities totaled $188.9 million at September 30, 2025. Enanta expects that its current cash, cash equivalents and marketable securities, as well as cash flows from its retained portion of future royalty revenue and proceeds from its October 2025 public offering, will be sufficient to meet the anticipated cash requirements of its existing business and development programs into fiscal 2029.

Virology

- Enanta's virology pipeline includes the leading portfolio in development for RSV treatment, consisting of zelicapavir and EDP-323, both of which received Fast Track designation from the U.S. Food and Drug Administration.
    - In September, Enanta reported data on zelicapavir, an oral, once-daily RSV N-protein inhibitor, which was evaluated in RSVHR, a Phase 2b, randomized, double-blind, placebo-controlled study in adults with RSV infection who were at high risk of complications. This includes patients older than 65 years and those with congestive heart failure, chronic obstructive pulmonary disease or asthma.
        - In the RSVHR study, a clinically meaningful improvement in time to complete resolution of all 13 RSV symptoms was observed for zelicapavir compared to placebo, with a benefit of 2.2 days for the overall efficacy population and 6.7 days for patients with congestive heart failure, chronic obstructive pulmonary disease, or age 75 years or older, termed the HR3 population, which comprised the majority (81%) of the efficacy population. Zelicapavir also showed an improvement in time to complete resolution on the 29-parameter total RiiQ™ symptom scale of 3.6 days for the efficacy population and 7.2 days for the HR3 population compared to placebo. Additionally, there was a 3.0-day faster time to complete resolution of lower respiratory tract disease (LRTD) symptoms in the HR3 population; however, no effect was observed on the time to resolution of the LRTD subset of four symptoms to mild, which was the primary endpoint. The study met the secondary endpoint of time to improvement in the Patient Global Impression of Severity (PGI-S) score, with a statistically significant 2-day faster resolution with zelicapavir compared to placebo. Importantly, a lower hospitalization rate was observed for patients treated with zelicapavir compared to placebo. The study met key secondary virology endpoints showing a robust antiviral effect. Zelicapavir demonstrated a favorable safety profile and was well-tolerated in the study.
        - In October, the Company presented data at the Infectious Diseases Society of America (IDSA) 2025 Conference (IDWeek™) highlighting its previously reported positive results from the Phase 2 study of zelicapavir in pediatric patients, including new data demonstrating that treatment with zelicapavir is associated with shortened time to complete resolution of RSV symptoms (defined as absent and discharged from hospital). A post-hoc analysis of time to complete resolution of symptoms showed an estimated Kaplan-Meier median of 6.99 days for zelicapavir versus 8.60 days for placebo. Similarly, an analysis of sustained resolution (defined as absent and remaining absent at all subsequent time points and discharged from hospital) resulted in 6.99 days for zelicapavir versus 10.68 days for placebo. The poster can be found on the Company's website here.
    - Enanta's second RSV candidate is EDP-323, an oral, once-daily RSV L-protein inhibitor, which can be used alone or in combination with other agents, such as zelicapavir, to potentially broaden the treatment window or addressable patient populations.
        - In October, the Company presented data at IDWeek™ on the previously disclosed Phase 2a human challenge study of EDP-323. A post-exposure prophylaxis (PEP) analysis was performed in subjects who were not infected by Day 5 after RSV exposure. In this population, 68 RSV-exposed, susceptible subjects were randomized to receive EDP-323 (low dose n=24, high dose n=21) or placebo (n=23). Of these subjects, 26% (6/23) of those who received placebo became infected versus 0% (0/45) of EDP-323 recipients ($p<0.001$). Evaluated separately, the two EDP-323 dosing groups' PEP effects were statistically significant (low dose $p=0.009$, high dose $p=0.022$) versus placebo. The poster can be found on the Company's website here.
        - An oral presentation of the EDP-323 challenge study was also featured at IDWeek™. In new data on clinical symptoms, which were assessed once-daily using the Respiratory Infection Intensity and Impact Questionnaire (RiiQ™), participants showed rapid (within the first 24 hours) and statistically significant improvements in RiiQ™ RSV symptoms and viral load after EDP-323 dosing. Compared to placebo, there were 73% ($p=0.0012$), 61% ($p=0.0010$), and 67% ($p<0.0001$) RiiQ™ total symptom score AUC reductions in 200mg, 600mg, and EDP-323 pooled recipients respectively. The presentation can be found on the Company's website here.

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.
    - Enanta nominated EPS-3903, a novel, potent and selective oral STAT6 inhibitor, as its lead development candidate for the treatment of atopic dermatitis and other diseases currently treated by dupilumab. Preclinical data show EPS-3903 exhibited potent nanomolar activity in binding and cellular assays and was highly selective for STAT6. Importantly, EPS-3903 showed rapid, continuous and complete (>90%) inhibition of phosphorylated STAT6 (pSTAT6) after oral dosing in mice. Further, EPS-3903 demonstrated efficacy comparable to dupilumab in multiple disease models. Specifically, in a house dust mite asthma model, EPS-3903 resulted in complete (>90%) inhibition of lung pSTAT6 and decreased inflammation comparable to dupilumab, including clinically relevant biomarkers of eosinophils and TARC in the lung and serum IgE. Additionally, in an MC903 atopic dermatitis mouse model, EPS-3903 demonstrated efficacy comparable to dupilumab, with complete (>90%) inhibition of pSTAT6 in the skin and spleen, as well as a robust decrease in serum IgE. EPS-3903 had favorable *in vitro* and *in vivo* ADME properties with once-daily dosing potential. The Company is currently performing scale-up and IND enabling activities and targeting an IND filing in the second half of 2026.
    - Enanta selected EDP-978, a novel, potent and selective oral KIT inhibitor, as its clinical candidate for the treatment of chronic spontaneous urticaria and potentially other mast cell driven diseases. EDP-978 demonstrated nanomolar potency in both binding and cellular assays, had sub-nanomolar activity *in vivo*, and high selectivity for KIT versus other kinases. EDP-978 also demonstrated good *in vitro* and *in vivo* ADME properties preclinically. The Company is on track to submit an IND in the first quarter of 2026.
    - Enanta plans to expand its immunology pipeline with the introduction of a third program in the fourth quarter of this year.

Corporate

- In August, Enanta filed a patent infringement action in the Unified Patent Court (UPC) of the European Union against Pfizer Inc. and certain of its subsidiaries. The suit seeks a determination of liability for infringement of European Patent No. EP 4 051 265 (the "'265 Patent") in connection with Pfizer's manufacture, use, and sale of Paxlovid™ (nirmatrelvir tablets; ritonavir tablets) in the 18 EU member states participating in the UPC. Under UPC procedures, a hearing on the infringement action is expected within the UPC's published 12-month target, with a decision rendered within weeks thereafter.
- In October, Enanta successfully closed an upsized underwritten public offering of 7,475,000 shares of common stock at $10.00 per share, including the full exercise of the underwriters' option to purchase an additional 975,000 shares. The gross proceeds from the offering, before deducting underwriting discounts and commissions and other offering expenses, were approximately $74.8 million.
- Enanta plans to issue its fiscal first quarter 2026 financial results press release on February 9, 2026.

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 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 September 30,		Twelve Months Ended September 30,	
	2025	2024	2025	2024
Revenue	$ 15,125	$ 14,607	$ 65,324	$ 67,635
Operating expenses				
Research and development	23,809	30,778	106,740	131,476
General and administrative	9,702	13,683	43,933	57,850
Total operating expenses	33,511	44,461	150,673	189,326
Loss from operations	(18,386)	(29,854)	(85,349)	(121,691)
Interest expense	(2,387)	(2,581)	(7,681)	(10,940)
Interest and investment income, net	2,105	3,249	9,481	14,843
Loss before income taxes	(18,668)	(29,186)	(83,549)	(117,788)
Income tax (expense) benefit	(32)	363	1,660	1,743
Net loss	$ (18,700)	$ (28,823)	$ (81,889)	$ (116,045)
Net loss per share				
Basic	$ (0.87)	$ (1.36)	$ (3.84)	$ (5.48)
Diluted	$ (0.87)	$ (1.36)	$ (3.84)	$ (5.48)
Weighted average common shares outstanding				
Basic	21,380	21,190	21,336	21,157
Diluted	21,380	21,190	21,336	21,157

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

	September 30, 2025	September 30, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 32,298	$ 37,233
Short-term marketable securities	156,566	210,953
Accounts receivable	6,882	6,646
Prepaid expenses and other current assets	8,590	12,413
Income tax receivable	—	31,999
Short-term restricted cash	—	608
Total current assets	204,336	299,852
Property and equipment, net	35,395	32,688
Operating lease, right-of-use assets	37,549	40,658
Long-term restricted cash	3,360	3,360
Other long-term assets	92	94
Total assets	$ 280,732	$ 376,652
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,948	$ 8,002
Accrued expenses and other current liabilities	12,751	13,547
Liability related to the sale of future royalties	30,710	34,462
Operating lease liabilities	3,146	1,524
Total current liabilities	48,555	57,535
Liability related to the sale of future royalties, net of current portion	111,132	134,779
Operating lease liabilities, net of current portion	54,757	53,943
Series 1 nonconvertible preferred stock	1,311	1,350

Other long-term liabilities	260	231
Total liabilities	216,015	247,838
Total stockholders' equity	64,717	128,814
Total liabilities and stockholders' equity	$ 280,732	$ 376,652

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