



## Enanta Pharmaceuticals Reports Financial Results for its Fiscal First Quarter Ended December 31, 2024

February 10, 2025

- *On Track to Report Topline Results for RSVHR, a Phase 2 Study of Zelicapavir in High-Risk Adults Infected with Respiratory Syncytial Virus (RSV), in 3Q 2025*
- *Advancing Immunology Portfolio with Ongoing IND Enabling Studies of KIT Inhibitor EPS-1421*
- *On Track to Announce STAT6 Development Candidate in 2H 2025*
- *Operations Supported by Cash and Marketable Securities Totaling \$216.7 Million at December 31, 2024, as well as Continuing Retained Royalties*

WATERTOWN, Mass.--(BUSINESS WIRE)--Feb. 10, 2025-- [Enanta Pharmaceuticals, Inc.](https://www.enantapharm.com) (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 first quarter ended December 31, 2024.

"2025 is primed to be a pivotal year for Enanta as we execute on multiple catalysts across our pipeline, including progression of our RSV compounds and expansion of our immunology portfolio. Recruitment for RSVHR, our Phase 2 study of zelicapavir in high-risk adults infected with RSV, is ongoing and we plan to report topline data in the third quarter of this year. Following the encouraging results from our pediatric RSV study, we look forward to working with regulators to align on the registration pathway for zelicapavir in children and await the results of RSVHR, a Phase 3 enabling trial for adults. With both zelicapavir and EDP-323, we have the leading portfolio of RSV candidates in clinical development today and are eager to develop potential first-in-disease and best-in-class treatments for patients suffering from RSV," said Jay R. Luly, Ph.D., President and Chief Executive Officer at Enanta Pharmaceuticals. "Moving forward, we will be exploring potential partnership opportunities to advance our RSV program. Simultaneously, we are working to ensure readiness for the next phase of RSV clinical development in a strategic and capital efficient manner, thereby extending our cash runway into fiscal 2028."

Dr. Luly added, "In parallel, we are rapidly advancing and expanding our immunology portfolio targeting Type 2 immune diseases, with an initial focus on indications with fast proof-of-concept. We are making progress to advance EPS-1421, our lead candidate for our KIT inhibition program, with the goal of developing a best-in-class, oral treatment for chronic spontaneous urticaria and other mast cell driven diseases. We are also excited about the progress in our STAT6 program, where we are leveraging our expertise in medicinal chemistry to develop novel, potent and selective oral inhibitors that block the IL-4/IL-13 signaling pathway, with an initial indication in atopic dermatitis and future expansion opportunities in asthma and other diseases. We expect to select a lead development candidate for STAT6 in the second half of this year and look forward to continuing to build out our immunology portfolio with the announcement of a third program this year. We have a busy year ahead with multiple opportunities to drive value for the company and move us closer to bringing important treatments to patients in need."

### Fiscal First Quarter Ended December 31, 2024 Financial Results

Total revenue for the three months ended December 31, 2024 was \$17.0 million and consisted of royalty revenue from worldwide net sales of MAVYRET®/MAVIRET®, AbbVie's eight-week treatment for chronic hepatitis C virus, compared to \$18.0 million for the three months ended December 31, 2023. The decrease in 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. This is 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 \$2.0 million for the three months ended December 31, 2024, as compared to interest expense of \$3.4 million for the three months ended December 31, 2023.

Research and development expenses totaled \$27.7 million for the three months ended December 31, 2024, compared to \$36.4 million for the three months ended December 31, 2023. The decrease was due to a decrease in expenses for Enanta's virology program due to timing of clinical trials in the company's RSV program and to a lesser extent, a decrease in costs associated with Enanta's COVID-19 program, as the company previously announced any further COVID-19 efforts would be in the context of collaborations.

General and administrative expenses totaled \$12.8 million for the three months ended December 31, 2024, compared to \$16.5 million for the three months ended December 31, 2023. The decrease was due to a decrease in legal expenses related to the company's patent infringement lawsuit against Pfizer.

Interest and investment income, net, totaled \$2.8 million for the three months ended December 31, 2024, compared to \$4.3 million for the three months ended December 31, 2023. The decrease was due to lower cash and investment balances year-over-year.

Enanta recorded an income tax benefit of \$0.4 million for the three months ended December 31, 2024, and \$0.6 million for the three months ended December 31, 2023. The income tax benefit in both periods was driven by interest earned on a pending \$28 million federal income tax refund.

Net loss for the three months ended December 31, 2024 was \$22.3 million, or a loss of \$1.05 per diluted common share, compared to a net loss of \$33.4 million, or a loss of \$1.58 per diluted common share, for the corresponding period in 2023.

Enanta's cash, cash equivalents and short-term marketable securities totaled \$216.7 million at December 31, 2024. Enanta expects that its current cash, cash equivalents and marketable securities, as well as its retained portion of future royalty revenue, will be sufficient to meet the anticipated cash requirements of its existing business and development programs into fiscal year 2028.

## Virology

### RSV

- Enanta aims to develop a first and leading RSV antiviral treatment portfolio to help all populations at high-risk for severe 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.
  - Zelicapavir is 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, 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 completion in the current Northern Hemisphere RSV season with topline data in the third quarter of 2025.
    - In December 2024, Enanta announced results from a Phase 2 randomized, double-blind, placebo-controlled study in hospitalized and non-hospitalized pediatric RSV patients aged 28 days to 3 years old. In the study of 96 patients, an antiviral effect was observed for the primary and secondary virology endpoints in the overall pooled efficacy population. The primary endpoint in Part 2 of the study, which focused on virology, showed a pronounced antiviral effect with a 1.4 log decline in viral load at Day 5 compared to placebo. Additionally, a rapid and robust virologic effect was observed in a prespecified subset of patients who were randomized within 3 days of symptom onset, with a 1.2 log decline in viral load at Day 5 compared to placebo. The study also showed that zelicapavir demonstrated a favorable safety profile and was well-tolerated in this pediatric population.
  - 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 results for EDP-323 in a Phase 2a challenge study of healthy adults infected with RSV, in which treatment with EDP-323 achieved highly statistically significant reductions in both viral load and clinical symptoms compared to placebo, as well as demonstrated a favorable safety and tolerability profile.
  - With positive results from both zelicapavir and EDP-323, Enanta has the most advanced portfolio of RSV therapeutic candidates, which provides important optionality and the potential for first-in-disease and best-in-disease development strategies. The company expects to work with regulators to align on the registration pathway for zelicapavir in pediatric patients and will look to complete RSVHR, a Phase 3 enabling trial in high-risk adults. In addition, Enanta will evaluate potential partnership opportunities to advance its RSV assets to the next stage of clinical development.

## Immunology

- Enanta's immunology portfolio 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 Inhibitors:
    - EPS-1421, Enanta's lead candidate, is a novel, potent and selective oral inhibitor of KIT, designed to treat chronic spontaneous urticaria and 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 has sub-nanomolar activity *in vivo*. EPS-1421 is also highly selective for KIT versus other kinases and, preclinically, has demonstrated good *in vitro* and *in vivo* ADME properties. Enanta is conducting scale-up activities and IND enabling studies in 2025.
  - STAT6 Inhibitors:
    - Enanta is advancing novel, potent and selective oral inhibitors of STAT6 for the treatment of type 2 immune driven diseases. The company will initially focus on atopic dermatitis and expand into other indications that block the IL-4/IL-13 signaling pathway, thereby addressing a primary driver of these diseases.
    - Enanta's prototype inhibitors demonstrate potent activity and high selectivity for STAT6 over other STATs in both biochemical and cellular assays. Additionally, the prototype inhibitors demonstrate systemic *in vivo* target engagement after *ex vivo* IL-4 stimulation. The company is conducting lead optimization activities and plans to select a STAT6 lead candidate in the second half of 2025.
  - Enanta plans to expand its presence in immunology with the introduction of a third program in 2025.

## Corporate

- On February 3, 2025, Enanta filed a notice of appeal with the United States Court of Appeals for the Federal Circuit related to a June 2022 lawsuit the company filed in the United States District Court for the District of Massachusetts 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 second quarter financial results press release on May 12, 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](http://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, 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 December 31,	
	2024	2023
Revenue	\$ 16,959	\$ 18,003
Operating expenses		
Research and development	27,656	36,371
General and administrative	12,846	16,518
Total operating expenses	40,502	52,889
Loss from operations	(23,543)	(34,886)
Interest expense	(1,962)	(3,441)
Interest and investment income, net	2,799	4,298
Loss before income taxes	(22,706)	(34,029)
Income tax benefit	416	622
Net loss	\$ (22,290)	\$ (33,407)
Net loss per share		
Basic	\$ (1.05)	\$ (1.58)
Diluted	\$ (1.05)	\$ (1.58)
Weighted average common shares outstanding		
Basic	21,238	21,088
Diluted	21,238	21,088

**ENANTA PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

**UNAUDITED**  
(in thousands)

	December 31, 2024	September 30, 2024
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 84,349	\$ 37,233
Short-term marketable securities	132,342	210,953
Accounts receivable	7,718	6,646
Prepaid expenses and other current assets	10,684	12,413
Income tax receivable	32,444	31,999
Short-term restricted cash	608	608
Total current assets	268,145	299,852
Property and equipment, net	37,368	32,688
Operating lease, right-of-use assets	39,675	40,658
Long-term restricted cash	3,360	3,360
Other long-term assets	94	94
Total assets	<u>\$ 348,642</u>	<u>\$ 376,652</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 4,726	\$ 8,002
Accrued expenses and other current liabilities	10,575	13,547
Liability related to the sale of future royalties	32,743	34,462
Operating lease liabilities	1,006	1,524
Total current liabilities	49,050	57,535
Liability related to the sale of future royalties, net of current portion	129,738	134,779
Operating lease liabilities, net of current portion	56,453	53,943
Series 1 nonconvertible preferred stock	1,350	1,350
Other long-term liabilities	235	231
Total liabilities	236,826	247,838
Total stockholders' equity	111,816	128,814
Total liabilities and stockholders' equity	<u>\$ 348,642</u>	<u>\$ 376,652</u>

View source version on [businesswire.com](https://www.businesswire.com/news/home/20250210108421/en/): <https://www.businesswire.com/news/home/20250210108421/en/>

**Media and Investors Contact:**

Jennifer Viera  
[jviera@enanta.com](mailto:jviera@enanta.com)

Source: Enanta Pharmaceuticals, Inc.