Enanta Pharmaceuticals Provides Update on its Research and Development Programs and 2026 Outlook

January 8, 2026

- *Continuing Phase 3 Enabling Activities, Including Discussions with U.S. Food & Drug Administration (FDA) Following Positive Phase 2b RSVHR Results for Zelicapavir, an N-Protein Inhibitor in Development to Treat Respiratory Syncytial Virus (RSV)*
- *Expanding Immunology Pipeline with New Discovery Program Focused on MRGPRX2 Inhibition Addressing High Unmet Need in Chronic Spontaneous Urticaria (CSU); On Track to Select a Development Candidate in 2H 2026*
- *Advancing EDP-978, an Oral, Once-Daily KIT Inhibitor Clinical Candidate; On Track to File an Investigational New Drug Application (IND) in 1Q 2026 and Report Phase 1 Data in 4Q 2026*
- *Progressing EPS-3903, an Oral, Once-Daily STAT6 Inhibitor Development Candidate; On Track to File an IND in 2H 2026*
- *Strong Financial Position Supported by Continuing Retained Royalties with Cash Runway Expected to Fund Operations into Fiscal 2029*
- *Company to Present 2026 Outlook at the 44th Annual J.P. Morgan Healthcare Conference on Wednesday, January 14 at 3:00 PM PT*

WATERTOWN, Mass.--(BUSINESS WIRE)--Jan. 8, 2026-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for viral infections and immunological diseases today announced updates on its research and development programs and highlighted upcoming key milestones for 2026.

“Building on the progress we achieved in our RSV and immunology portfolios this past year, we enter 2026 with strong momentum as we continue to expand our pipeline and deliver on key milestones,” said Jay R. Luly, Ph.D., President and Chief Executive Officer at Enanta Pharmaceuticals. “We are eager to advance our RSV portfolio with the progression of both zelicapavir and EDP-323. We look forward to continuing our discussions with the FDA to align on an adult Phase 3 study design and solidify next steps for zelicapavir’s registration path. With positive data from both zelicapavir and EDP-323 in hand, we continue to have the leading portfolio of RSV therapeutics, offering broad optionality and the potential for first- and best-in-disease treatments.”

Dr. Luly continues, “Today, we are pleased to announce our third immunology program, focused on developing oral MRGPRX2 inhibitors for type 2 immune driven diseases, with an initial focus on CSU and other mast cell driven diseases, with other future expansion opportunities. MRGPRX2 signaling is a critical driver of inflammation, and inhibitors have the potential for strong efficacy with best-in-disease safety. This program represents a meaningful addition to our growing immunology portfolio, and we look forward to nominating a development candidate in the second half of 2026. In parallel, we are advancing EDP-978, our oral, once-daily KIT inhibitor clinical candidate with the goal of filing an IND in the first quarter and reporting Phase 1 data in the fourth quarter of this year. We are also progressing EPS-3903, our oral, once-daily STAT6 development candidate with plans to file an IND in the second half of 2026 and advance into the clinic shortly thereafter. With programs in KIT, STAT6 and MRGPRX2 inhibition, we are leveraging our proven expertise in small molecule drug discovery and development to build a leading immunology portfolio focused on type 2 immune driven diseases where there is a clear unmet need for convenient, safe and efficacious oral treatments. Finally, our strong cash position, with runway into fiscal 2029, provides us the resources to continue to build value by delivering highly differentiated therapeutics through innovative small molecule drug discovery.”

Pipeline Updates

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 FDA.
  - Enanta most recently evaluated zelicapavir, an oral, once-daily RSV N-protein inhibitor, in RSVHR, a Phase 2b study in a high-risk adult outpatient population, including the elderly and/or those with asthma, chronic obstructive pulmonary disease, or congestive heart failure. In September 2025, the Company announced positive data from the 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 6.7 days for patients with congestive heart failure, chronic obstructive pulmonary disease or age 75 or older, termed the HR3 population. Zelicapavir also showed an improvement in time to complete resolution on the 29-parameter total RiiQ™ symptom scale of 7.2 days for the HR3 population compared to placebo. The study met key secondary endpoints, including a reduction in hospitalization and antiviral effects. Zelicapavir has been dosed in more than 700 people to date and continues to be well-tolerated with a favorable safety profile.
    - Enanta is continuing Phase 3 enabling activities, including aligning with the FDA on an adult Phase 3 trial design and overall registration path. In parallel, the Company is exploring potential business development opportunities related to its RSV program.

- Enanta's second RSV candidate, EDP-323, is 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 on a post-exposure prophylaxis analysis performed in subjects who were not infected by Day 5 after RSV exposure in the EDP-323 human challenge study. The data showed the potential for EDP-323 to be effective in preventing RSV infection when initiated up to five days after RSV exposure, building on the previously reported EDP-323 challenge study treatment data.

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 today announced its third immunology program targeting MRGPRX2, a non-canonical G-Protein-Coupled-Receptor (GPCR) expressed predominantly on mast cells. Inhibiting MRGPRX2 may have potential to address multiple chronic inflammatory diseases including urticaria, asthma, prurigo nodularis and others. Currently, Enanta is advancing novel, potent and selective oral inhibitors of MRGPRX2. The Company's prototype MRGPRX2 inhibitors exhibit potent inhibition *in vitro* and *in vivo*. Specifically, they demonstrate MRGPRX2 inhibition with nanomolar potency (EC_{50} of 1-2nM) in cellular assays and prevent skin mast cell activation in humanized MRGPRX2 mouse models. Further, the Company's MRGPRX2 prototype inhibitors show potent activity across multiple MRGPRX2 agonists. These prototypes are highly selective for MRGPRX2 versus other GPCRs. Finally, these prototypes show favorable *in vitro* and *in vivo* ADME properties supporting once daily dosing. Enanta continues to evaluate multiple compounds in preclinical studies and expects to select a development candidate in the second half of 2026.
  - Enanta recently 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 demonstrates nanomolar potency in both binding and cellular assays, sub-nanomolar activity *in vivo*, and high selectivity for KIT versus other kinases. EDP-978 also exhibits favorable *in vitro* and *in vivo* ADME properties preclinically. The Company is on track to submit an IND in the first quarter, with topline Phase 1 data expected in the fourth quarter of 2026.
  - In November, 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 exhibits nanomolar activity in binding and cellular assays and high selectivity for STAT6. Importantly, EPS-3903 shows rapid, continuous and complete (>90%) inhibition of phosphorylated STAT6 (pSTAT6) after oral dosing in mice. Further, EPS-3903 demonstrates efficacy comparable to dupilumab in multiple disease models. Specifically, in a house dust mite asthma model, treatment with EPS-3903 results 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 demonstrates 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 has 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.

Corporate

- In August 2025, 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 to occur within the UPC's published 12-month target, with a decision rendered within weeks thereafter. Enanta expects to provide an update on the UPC litigation in the second half of 2026.

The Company expects the following milestones across its pipeline in 2026:

- *Virology*
  - Respiratory Syncytial Virus
    - Align with FDA on adult Phase 3 design and registration path in 2Q 2026
    - Prepare for a Phase 3 study of zelicapavir in high-risk adults in 2H 2026
    - Explore business development opportunities for RSV assets

- *Immunology*
  - KIT Program
    - File IND for EDP-978 in 1Q 2026
    - Report Phase 1 data for EDP-978 in 4Q 2026

- STAT6 Program
  - File an IND for EPS-3903 in 2H 2026
- MRGPRX2 Program
  - Nominate development candidate in 2H 2026

Webcast Information

Enanta will provide further details on these updates at the 44th Annual J.P. Morgan Healthcare Conference on Wednesday, January 14, 2026 at 3:00 p.m. PT. A live webcast of the presentation will be accessible by visiting the “Events and Presentations” section on the “Investors” page of Enanta’s website at www.enanta.com. A replay of the webcast will be available following the presentation and will be archived for approximately 30 days.

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, STAT6 and MRGPRX2 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, STAT6 and MRGPRX2 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 limited 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, 2025, 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.

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