Henlius Delivers Strong 2026 Interim Financial Results, Accelerates Global Validation Under Globalisation 2.0 Strategy

Shanghai-based Chinese biopharmaceutical company Henlius has released its interim results for the first half of 2026, reporting robust revenue expansion.



Henlius —— A Chinese Biopharmaceutical Company Driving Innovation Worldwide

SHANG HAI, CHINA, September 17, 2026 /EINPresswire.com/ -- Shanghai-based Chinese biopharmaceutical company Henlius has released its interim results for the first half of 2026, reporting robust revenue expansion, growing profitability and major cross-border milestones for its flagship anti-PD-1 therapy serplulimab.

For the six-month reporting period ending June 30, 2026, total revenue reached RMB 3.5882 billion, a year-on-year increase of 27.3%. Net profit stood at RMB 430.4 million, up 10.3% year-over-year. Non-IFRS profit totalled RMB 572.3 million (+46.7% YoY), while adjusted EBITDA (non-IFRS measure) hit RMB 904.1 million, rising 35.2% compared with the same period of 2025. All core financial metrics trended upward, underpinned by expanding global sales of marketed products and lean end-to-end operational execution across the value chain.

Global Commercial Momentum Builds, Henlius Expands International Footprint
Henlius now counts 10 marketed products approved across more than 60 countries and regions throughout Asia, Europe, Latin America, North America and Oceania, benefiting over 1.1 million patients worldwide. Global product sales for H1 2026 reached RMB 2.9386 billion (+14.9% YoY). Notably, ex-China product revenue surged 159.4% year-on-year to RMB 105.3 million; ex-China product profit reached RMB 59.5 million, more than quadruple the figure recorded in H1 2025, demonstrating accelerating global commercial value generation.

Global Traction for Innovative Immuno-oncology Asset Serplulimab
Serplulimab, marketed as Hetronifly® in Europe and HANSIZHUANG in mainland China,

generated global sales of RMB 597.5 million during the first half of 2026. In June 2026, serplulimab obtained approval from China's NMPA for the perioperative treatment of gastric cancer. The therapy holds two distinct global-first regulatory milestones: it is the world's first anti-PD-1 monoclonal antibody approved for first-line extensive-stage small-cell lung cancer (ES-SCLC), as well as the world's first and only anti-PD-1 monoclonal antibody approved for perioperative treatment of gastric cancer, filling two longstanding unmet clinical gaps. Internationally, serplulimab has obtained marketing clearances in over 50 countries and regions. Within the European Union, serplulimab has been approved for four indications: extensive-stage small-cell lung cancer (ES-SCLC), oesophageal squamous-cell carcinoma (ESCC/OSCC), advanced non-squamous non-small-cell lung cancer (nsqNSCLC) and advanced squamous non-small-cell lung cancer (sqNSCLC). The medicine is now reimbursed through national public healthcare systems across 12 European nations including the United Kingdom, Germany, Italy, Spain and Sweden.

Biosimilar Portfolio Advances Across Key Global Markets

Henlius' breast-cancer biosimilar franchise maintained strong commercial momentum, delivering global sales totalling RMB 1.6983 billion in H1 2026. HANBEIYOU (pertuzumab; POHERDY® in the U.S. and EU) gained marketing authorisations from both the European Commission and China's NMPA in early 2026, making it the first and only Chinese-developed pertuzumab biosimilar approved in China, the United States and the European Union. Combined with HANQUYOU (trastuzumab biosimilar), it has been the first Chinese-developed trastuzumab-plus-pertuzumab dual HER2-targeted regimen approved across China, the U.S. and the EU.

HLX04, the bevacizumab biosimilar commercialised as Hanbeitai in China, is currently under the U.S. FDA's Biologics License Application review. Its indications approved globally include metastatic colorectal cancer, non-small cell lung cancer, recurrent glioblastoma, hepatocellular carcinoma, epithelial ovarian cancer and cervical cancer.

During 2026, Henlius has sealed three major global strategic partnership agreements to execute its Globalization 2.0 roadmap: granting Eisai exclusive rights for serplulimab commercialization in Japan; collaborating with Abbott to broaden serplulimab's reach across Asia-Pacific, Africa, Central Asia and Eastern Europe; and entering a wide-ranging biosimilar alliance with Sandoz covering up to ten assets for global markets. The firm is building a hybrid commercial structure combining in-house international teams alongside strategic third-party partners.

Innovation Pipeline Progress and R&D Investment

Total R&D expenditure for the first half of 2026 reached RMB 1.4507 billion, representing a 45.7% year-on-year increase. Henlius operates multiple proprietary technology platforms including next-generation immuno-oncology, Hanjugator ADC, multi-specific T-cell engager (TCE), and AI-powered discovery tools, with more than 50 early-stage pipeline molecules under development across oncology, immunology, neuroscience and metabolic disease areas.

HLX43, a potential best-in-class (BIC) PD-L1 ADC with broad therapeutic potential across multiple solid tumors, continues to advance global Phase 2 and Phase 2/3 multi-centre trials in non-small-cell lung cancer across China, Europe, the United States, Japan and Australia. Global enrollment across all HLX43 studies has exceeded 1500 patients to date. Other key pipeline assets include

dulpatatug (HLX22, novel-epitope anti-HER2 mAb) and its international Phase 3 head-to-head trial for HER2-positive gastric cancer has achieved first-patient enrollment across a broad geographic footprint, including China, the U.S., Europe, Japan, Australia, South Korea, and Latin America. A suite of next-generation investigational candidates including tetraspecific and trispecific T-cell engagers, bispecific ADCs and small-molecule inhibitors are moving forward, with several IND applications scheduled for submission in H2 2026.
Under its parallel China-U.S. biosimilar development strategy, several biosimilar candidates are advancing through parallel clinical development in China and the U.S., with multiple programs achieving first-patient dosing milestones in both markets.

Manufacturing, Regulatory and Long-Term Outlook
Henlius has built integrated global capabilities spanning R&D, clinical development, regulatory affairs, manufacturing and commercialization, as it builds its CMNC operating model. During H1 2026, the company secured 32 new clinical-trial approvals and 25 marketing authorisations covering nearly 50 countries and territories worldwide. Its biomanufacturing network has completed more than 1400 GMP-compliant commercial production batches, successfully passing more than 100 on-site inspections and audits conducted by global regulatory authorities and international partners, with a 100% pass rate. Nine first commercial shipments and 18 batch shipments to ex-China markets have also been completed in the reporting period.
Looking toward 2030, Henlius aims to launch an additional ten products globally, with more than five expected to reach European and U.S. markets, on its path toward becoming a globally influential innovative biopharmaceutical company.

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