

Merck & Co. - Replacing Growth Before the Keytruda Transition

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Decision scope: Hypothetical outside-investor assessment of Merck's portfolio and pipeline strategy

Case convention: This classroom scenario does not describe a private discussion or recommendation made by Merck management. Company explanations and expectations are attributed. No evidence after the cutoff is used.

The assignment

You are an outside strategy adviser preparing a confidence assessment for an investment committee. Merck says its "One Pipeline" strategy combines internally generated research with external science obtained through licenses, collaborations, venture activity and acquisitions. At the same time, the company expects Keytruda to face biosimilar competition beginning as early as December 2028 and expects U.S. price-setting effects in 2029.

Should the committee raise, hold or lower its confidence that Merck's portfolio and pipeline strategy can sustain growth through this transition? Build the strongest case for your view and identify evidence that would change it. Distinguish launches and current sales from pipeline potential, acquisition charges from returns, and company expectations from outcomes. No valuation or financial model is required.

Merck's current portfolio

Merck reported worldwide sales of \$65.0 billion in 2025, up 1% reported and 2% excluding foreign exchange. The year contained sharply different regional results: U.S. sales grew 13% to \$36.5 billion, while international sales declined 11% to \$28.5 billion. Oncology, cardiometabolic and respiratory, diabetes and Animal Health contributed to growth; declines in vaccines, immunology and virology offset some of it. [1]

Keytruda remained the largest concentration. Merck states that it represented 49% of total 2025 sales. In the first half of 2026, combined Keytruda and Keytruda Qlex sales were \$16.4 billion, up 8% reported and 6% excluding foreign exchange. Merck attributes growth to demand, additional indications and pricing, but H1 sales also included an approximately \$250 million favorable effect from wholesaler-purchase timing. Q2 Keytruda Qlex sales were \$463 million. Qlex is a subcutaneous presentation of pembrolizumab, not a separate drug franchise. [1-2]

Other products offer evidence of potential breadth. Winrevair sales reached \$1.443 billion in 2025 and \$588 million in Q2 2026, a 75% year-over-year increase. Animal Health sales were \$1.775 billion in Q2, up 8% reported and 5% excluding currency. By contrast, Gardasil/Gardasil 9 sales fell 39% in 2025 to \$5.233 billion, primarily due to lower China sales. Merck paused

China shipments in February 2025 after elevated inventory at its commercialization partner and said it could not predict when shipments would resume. Q2 2026 global Gardasil sales grew 4%, helped by demand in Asia-Pacific and Europe and European tender timing, but lower demand in some international markets remained an offset. [1-3]

Merck's Q2 2026 worldwide sales were \$16.6 billion, up 5% reported and 4% excluding foreign exchange; first-half sales were \$32.9 billion, up 5% and 3% excluding currency. Growth came from oncology, cardiometabolic and respiratory, and Animal Health, partly offset by declines in diabetes and infectious diseases and lower year-to-date vaccine sales. These are current results, not evidence by themselves that the portfolio will replace Keytruda's eventual erosion. [2-3]

The expected Keytruda transition

Merck expects Keytruda to be materially affected by biosimilar competition between 2028 and 2029, potentially beginning in December 2028. The company identifies patent litigation and patent terms as relevant to timing; it expects European market exclusivity loss in 2031. Separately, Merck expects Keytruda to be selected for a later round of U.S. Inflation Reduction Act price setting, with a new price effective January 1, 2029, materially lowering U.S. sales thereafter. These are the company's expectations as of the cutoff, not certain dates or a quantified erosion forecast. [1]

The challenge is therefore not simply to find new candidates. New products must advance through trials and regulatory review, win reimbursement and adoption, and contribute enough durable demand to matter at portfolio scale. Existing products can also grow through new indications or delivery formats, but their growth, pricing and competitive positions may change over time.

One Pipeline and business development

Merck describes One Pipeline as a unified approach that combines internal research with external science across early research, investment, licensing, collaboration and acquisition. The June 2026 company explanation calls it a science-led strategy; that statement describes management's intent, not independent evidence of productivity. [4]

Recent transactions span different stages and business areas:

- Merck completed the acquisition of Verona Pharma in October 2025 for approximately \$10 billion, adding approved COPD medicine Ohtuvayre. Q2 2026 Ohtuvayre sales were \$204 million; Merck said the quarter benefited from specialty-pharmacy purchase timing and expected that effect to unwind in Q3. [5]
- Merck completed the Cidara acquisition in January 2026. Its lead candidate, CD388, is an investigational long-acting antiviral in Phase 3. The Q2 filing records a \$9.0 billion acquired in-process research and development charge for Cidara; Merck's release separately estimated first-12-month EPS pressure from advancing and financing the program. The accounting charge is not a transaction price or a measure of returns. [2, 6]
- Merck acquired clinical-stage oncology company Terns in May 2026 for \$6.8 billion. Its lead candidate, MK-4208, was in a Phase 1/2 trial. Merck recorded a \$5.7 billion Q2 charge associated with the acquisition. [2-3]
- In July 2026, Merck acquired poultry-technology company TARGAN for approximately \$650 million, adding automated poultry solutions and vaccine-delivery technology to Animal Health. [2]

These deals may add capabilities, products or scientific options. They also differ in maturity, business fit, risk and time to potential commercialization. The available disclosures do not establish their eventual approval, commercial success, synergies or returns.

Internal investment and execution

Merck reported \$15.8 billion of total R&D expense in 2025, down 12% from 2024 primarily because of lower business-development charges. Direct human-health R&D performed by Merck Research Laboratories was \$10.8 billion. Q2 2026 R&D expense was \$9.7 billion and H1 was \$22.3 billion, heavily affected by acquired IPR&D charges for Terns and Cidara. These expense totals are not a clean measure of internally performed research over time. [1-2]

Merck's 2025 restructuring program estimated \$3.0 billion in total pretax costs and \$1.7 billion of annual savings substantially realized by the end of 2027; the company said savings would be reinvested in strategic growth areas. Those are management estimates, not realized savings or proof of future pipeline output. [1]

What research can and cannot tell you

Becker, Beukel and De Jong (2017) studied 12 large pharmaceutical companies, including Merck, over 1990-2013. Their dataset included 568 relevant acquisitions, 1,270 R&D-related alliances and 318 U.S. new molecular entity or biologic approvals. In five-year-lagged panel models, biotech acquisitions were negatively associated with approval counts; alliances, particularly pharmaceutical alliances, were positively associated. Some relationships varied with R&D intensity. The findings invite questions about internal capability and deal form, but they do not predict Merck's current transactions: the sample is historical, large-scale M&A was excluded, approvals are not commercial value, and the analysis is observational. [7]

McCarthy, Aalbers and Kearney (2025) studied alliance-to-acquisition transitions among 351 pharmaceutical firms, 2,661 firm-year observations, 1,784 acquisitions and 65,523 patent applications during January 1990-January 2015. Their negative-binomial models used firm and year dummies. They found more incremental innovation after transitions but no statistically significant effect on breakthrough innovation. Patents are an imperfect proxy for approved and commercially successful medicines, and the results concern acquisition of prior alliance partners-not all forms of external innovation. [8]

Questions for discussion

1. Should the committee raise, hold or lower confidence that Merck can sustain growth through the expected Keytruda transition? What is the strongest evidence against your view?
2. Which current products and pipeline assets provide the most relevant evidence of portfolio broadening? Which are mature launches, acquired revenue or clinical options?
3. What can the 2025 and H1 2026 results tell you about durability? How do foreign exchange, wholesaler or tender timing, channel inventory, and acquisition charges affect interpretation?
4. How should investors assess a pipeline strategy that combines internal R&D, licensing, collaborations and acquisitions? What does the academic evidence help you ask, and what does it not answer?
5. Which disclosures or milestones would most change your confidence in either direction?

Sources

- [1]** Merck & Co., [FY2025 Form 10-K](#), filed February 24, 2026. Relevant printed pages: MD&A pp. 47-63; risk factors pp. 27-35; product, patent and pipeline discussion pp. 1-26 and 53-59.
- [2]** Merck & Co., [Q2 2026 Form 10-Q](#), filed August 7, 2026, quarter ended June 30, 2026. MD&A pp. 30-41; product results pp. 31-38; business development, segment and R&D disclosures.
- [3]** Merck & Co., [Q2 2026 results and pipeline release](#), August 4, 2026.
- [4]** Merck & Co., [One Pipeline strategy explanation](#), June 8, 2026.
- [5]** Merck & Co., [Verona Pharma acquisition completion](#), October 7, 2025.
- [6]** Merck & Co., [Cidara acquisition completion](#), January 7, 2026.
- [7]** Becker, L., Beukel, K. & De Jong, M. (2017), "The moderating role of absorptive capacity and the differential effects of acquisitions and alliances on Big Pharma firms' innovation performance," *PLOS ONE*, 12(2), e0172488. [Full text](#). Reading depth, locators and limitations in the research source register.
- [8]** McCarthy, K., Aalbers, R. & Kearney, C. (2025), "Organising for innovation: alliance-to-acquisition transitions and patent production," *The Journal of Technology Transfer*, 50, 2837-2866. [Full text](#). Reading depth, locators and limitations in the research source register.