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Strategic and Financing Partner to Global Healthcare

Vital Signs: A Pulse Check on the Healthcare Market

Political Economy Update – Markets, Policy and Deal Activity

DNB // Back Bay | Investment Banking Division

May 2025

Executive Summary

Macro

US markets enter Q2 2025 recalibration phase amid policy constraints and global de-risking

- April opened with market dysfunction as trade war headlines challenged optimistic forecasts for 2025 US growth and S&P 500
- Treasury Secretary Bessent's proposed 90-day pause helped stabilize sentiment and reopen capital markets
- Business activity and inventories were front-loaded in anticipation of potential tariffs
- US economic growth is normalizing following four years of strong consumer demand, five years of aggressive fiscal policy, and persistent inflation above target
- Global investors, including European institutions and US hedge funds, sharply reduced US equity exposure, reversing most Q4 2024 inflows
- Institutional liquidity has improved, and a lighter equity issuance calendar supports a more constructive outlook for Q2 2025

Regulatory

Current administration is driving a full-spectrum overhaul of US healthcare policy, reshaping the life sciences ecosystem through budget cuts, leadership churn, tariffs, and pricing reform

- **Budget cuts:** Layoffs and budget cuts to the FDA, NIH, and CDC may delay regulatory timelines and dampen scientific innovation
- **Tariffs:** Experts warn that pharma and medical device import tariffs could disrupt supply chains, pressure earnings, and raise prices
- **Development:** Policy efforts aim to accelerate rare disease R&D, streamline generics approvals, and integrate AI into drug reviews
- **Pricing:** Executive orders aim to reduce drug prices, but timelines, implementation, and impact remain uncertain
- **Outlook:** Policy shifts have made institutional investors more cautious, while big pharma stays active in deal making—albeit with greater selectivity and discipline

Healthcare Market Activity

US & Europe healthcare deal making in 2025 started the year on a promising note due to a renewed sense of optimism for the sector; however, activity soon faded in the face of tariffs, budget cuts, and regulation uncertainty

- **M&A:** Rebounded vs. lows of H2 2024 with fewer but larger transactions as acquirors focused on commercial-stage companies
- **Licensing:** Skewed toward discovery / pre-clinical assets with lower upfront payments
- **IPO:** Raised $2.5B across 13 offerings (half of which were commercial) with mixed post-listing performance before the market stalled
- **Follow-on and PIPE/RDO:** Proceeds declined ~38% (follow-ons) and ~37% (PIPEs / RDOs) in Q1 2025 vs. Q4 2024, highlighting the challenges in raising capital in this environment
- **Venture:** Remained flat on a YoY basis at $5.4B thanks to larger average round sizes but seed financing plummeted to record lows

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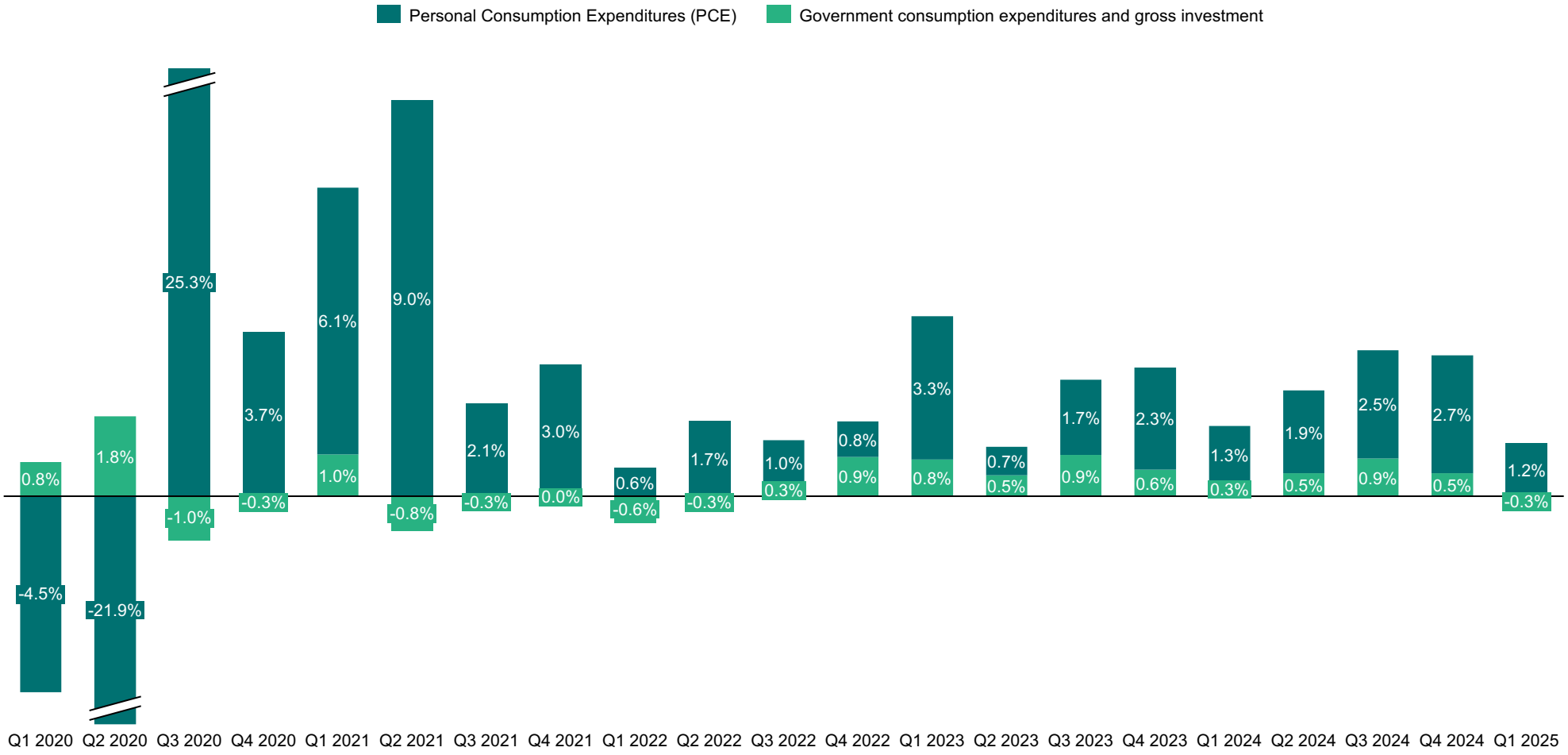
US GDP has been supported by government & personal consumption, however, the extent to which these will continue to support growth in H2 2025 is less certain

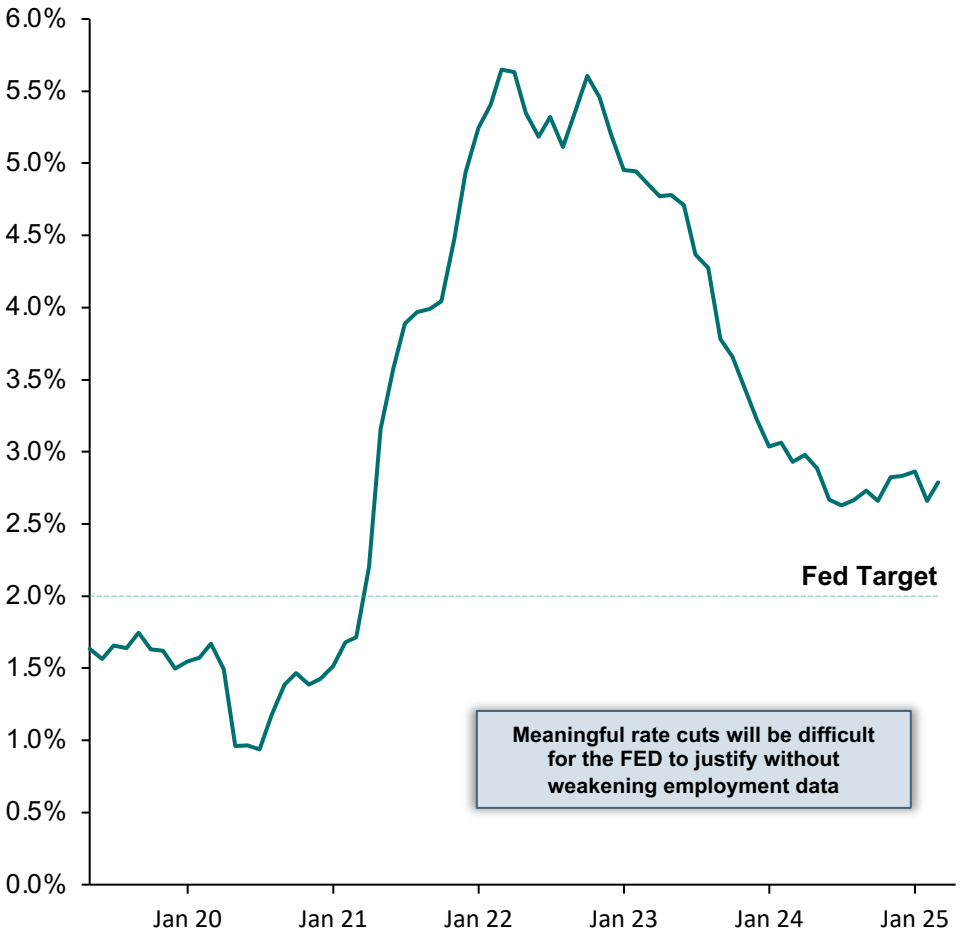
Quarter over Quarter Change to Personal & Government Expenditure



Sources: Bureau of Economic Analysis

Fed maintains rates as risks to inflation and unemployment rise, signaling patience and data dependence in the face of evolving uncertainties

US Personal Consumption Expenditure (PCE) Core Price Index YoY



Key Takeaways from May 7th Fed Meeting

- Fed held the federal funds rate steady at 4.25–4.50% in line with market expectations, reflecting a wait-and-see stance amid ongoing economic resilience
- The overall policy approach remains moderately restrictive as the Fed balances solid growth with persistent inflationary pressures
- Chair Powell emphasized patience and a need for clearer data trends before considering any changes to monetary policy direction
- FOMC members were unanimous in supporting a cautious approach
- Inflation remains somewhat elevated while the labor market continues to show strength, reducing urgency for immediate rate action
- Fed flagged an increase in risk for both rising unemployment and sticky inflation, underscoring a challenging policy tradeoff ahead
- Trade policy developments and potential supply chain disruptions were acknowledged as material risks that could shift the outlook
- Powell reaffirmed central bank independence, dismissing any influence from political actors or recent fiscal policy developments
- Market reactions were mixed with initial rate relief driving gains before sentiment reversed during Powell's press conference

The Fed is holding rates steady and signaling no imminent moves, reinforcing the need for financial decision makers to plan for a prolonged higher-rate environment amid growing macro uncertainty

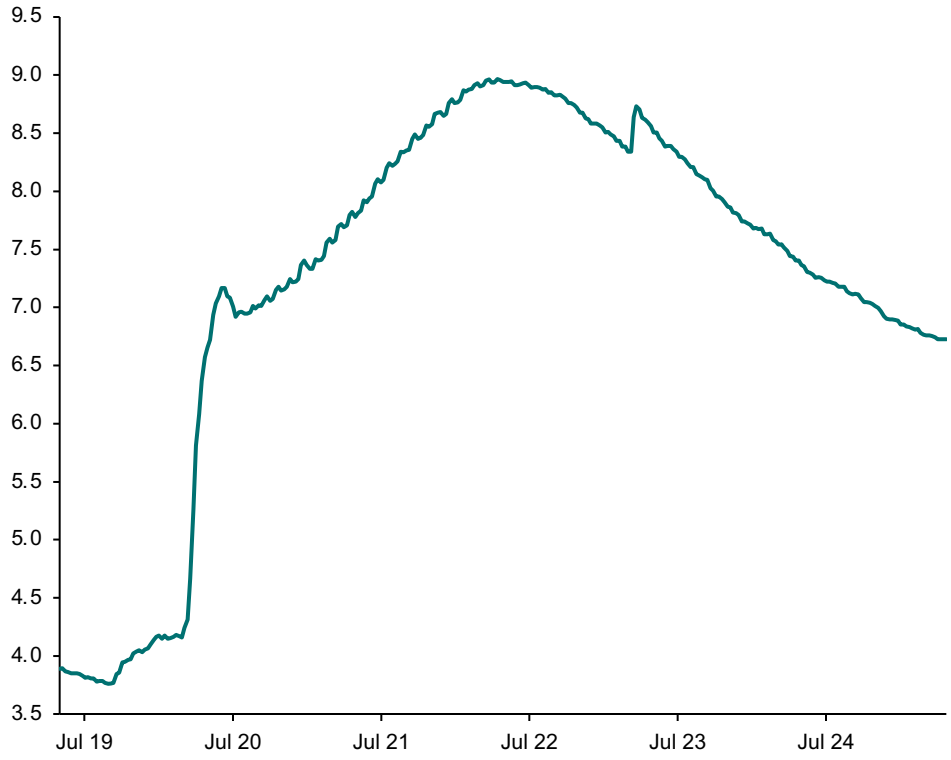
Sources: DNB Carnegie research, Bloomberg

If a bear market occurs, the 2020 33-day downturn is not a relevant comparison, as Fed policy will respond differently

S&P 500 Bear Markets Since 1928

Peak Date	Trough Date	Peak Price ($)	Trough Price (S)	Percent Loss (%)	Number of Days[2]
9/7/1929	11/13/1929	31.92	17.66	-44.7	67
4/10/1930	6/1/1932	25.92	4.40	-83.0	783
9/7/1932	2/27/1933	9.31	5.53	-40.6	173
7/18/1933	10/21/1933	12.20	8.57	-29.8	95
2/6/1934	3/14/1935	11.82	8.06	-31.8	401
3/6/1937	3/31/1938	18.68	8.50	-54.5	390
11/9/1938	4/8/1939	13.79	10.18	-26.2	150
10/25/1939	6/10/1940	13.21	8.99	-31.9	229
11/9/1940	4/28/1942	11.40	7.47	-34.5	535
5/29/1946	10/9/1946	19.25	14.12	-26.6	133
6/15/1948	6/13/1949	17.06	13.55	-20.6	363
7/15/1957	10/22/1957	49.13	38.98	-20.7	99
12/12/1961	6/26/1962	72.64	52.32	-28.0	196
2/9/1966	10/7/1966	94.06	73.20	-22.2	240
11/29/1968	5/26/1970	108.37	69.29	-36.1	543
1/11/1973	10/3/1974	120.24	62.28	-48.2	630
11/28/1980	8/12/1982	140.52	102.42	-27.1	622
8/25/1987	12/4/1987	336.77	223.92	-33.5	101
3/24/2000	10/9/2002	1527.46	776.76	-49.1	929
10/9/2007	3/9/2009	1565.15	676.53	-56.8	517
2/19/2020	3/23/2020	3386.15	2237.40	-33.9	33
1/3/2022	10/12/2022	4796.56	3577.03	-25.4	282

Fed Balance Sheet (USD trillion)

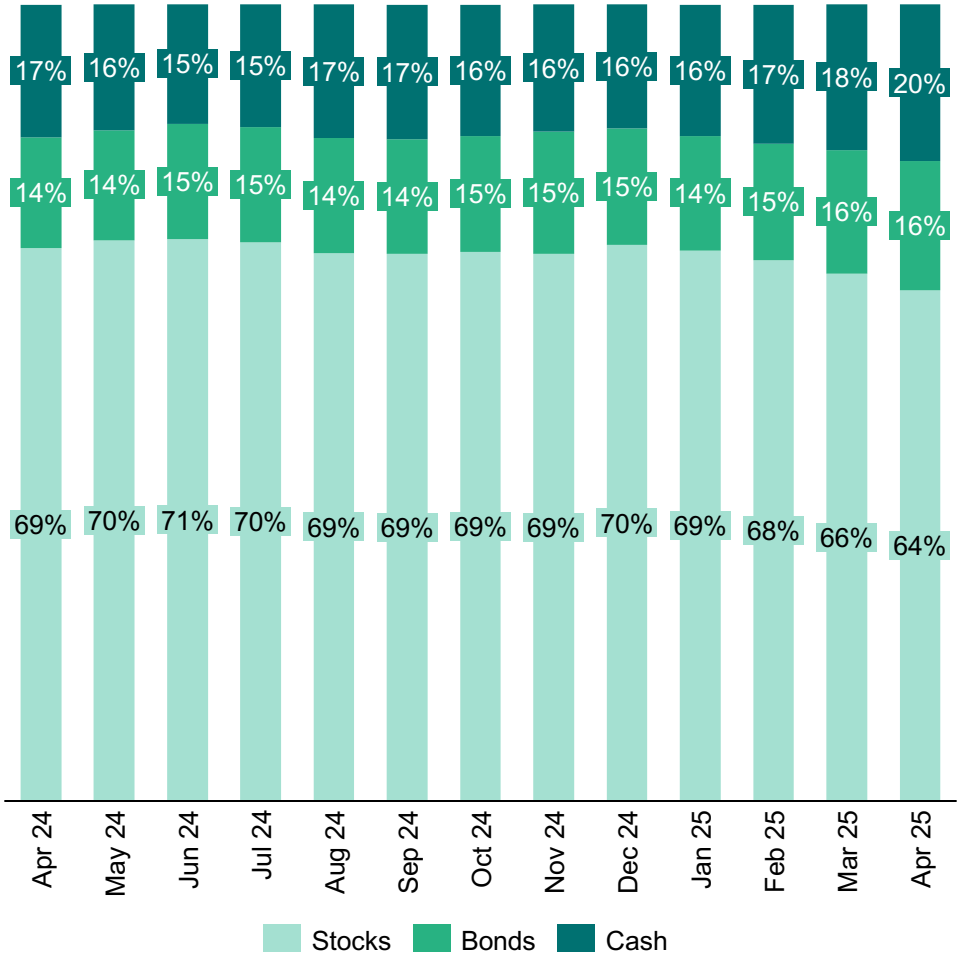


In response to the COVID-19 induced downturn in 2020, the Fed expanded its balance sheet by over $3 trillion. Should another downturn occur, consensus among economists suggests the Fed may be more hesitant to pursue similar measures given its current focus on balance sheet normalization.

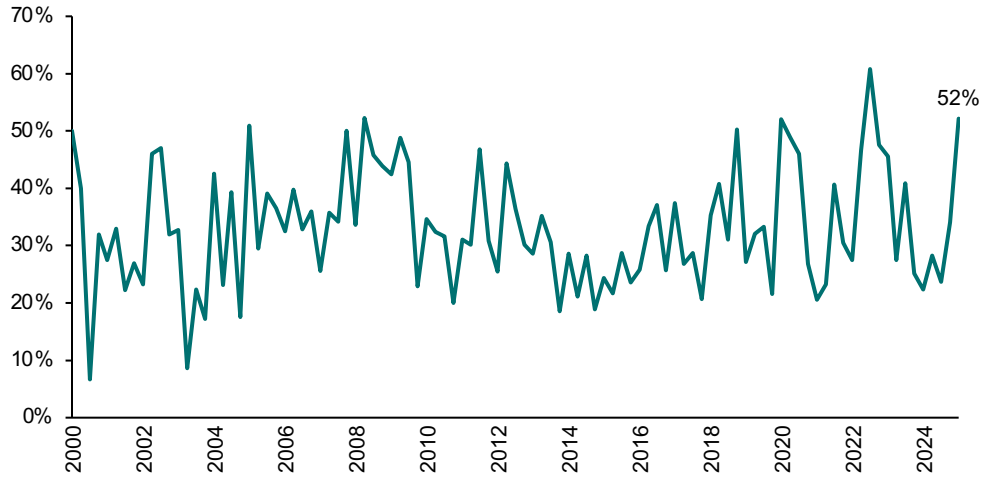
Fed Balance Sheet (USD trillion)

Rising retail pessimism mirrors consumer confidence, with 52% of retail investors now bearish as Consumer Confidence index falls to 57 (MCSI)

Retail Investor Allocation: Reducing Equities, More Cash



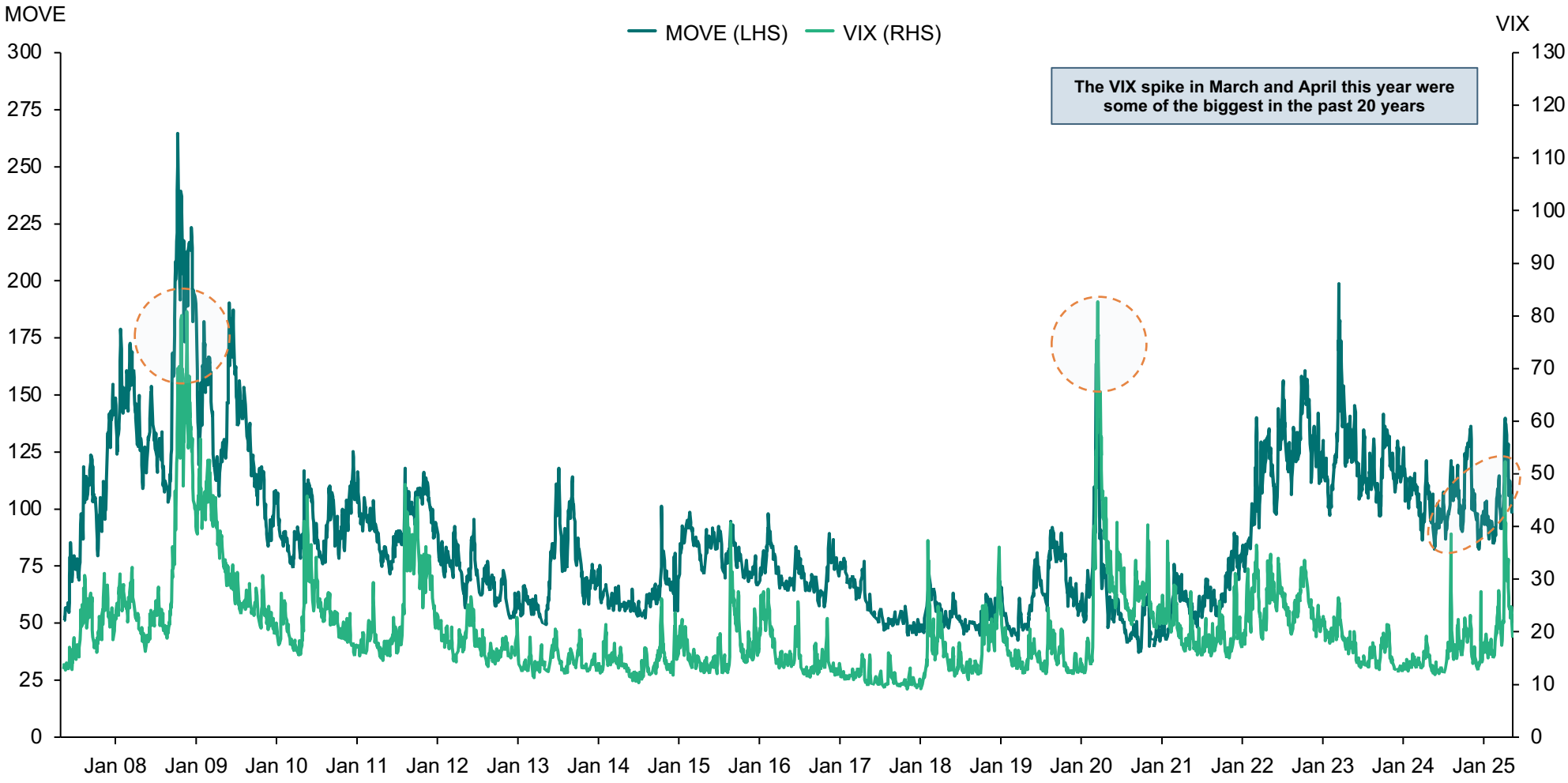
% of Retail Investors Who Are Bearish



US Consumer Confidence Is Down (MCSI[1])

1. Michigan Consumer Sentiment Index (MCSI) is a key economic indicator that reflects consumer sentiment in the economy (a higher value indicates greater optimism and confidence)
Sources: Bloomberg, AAII, University of Michigan

After three years of lagging volatility, US market surged starting last summer, reaching historically high levels

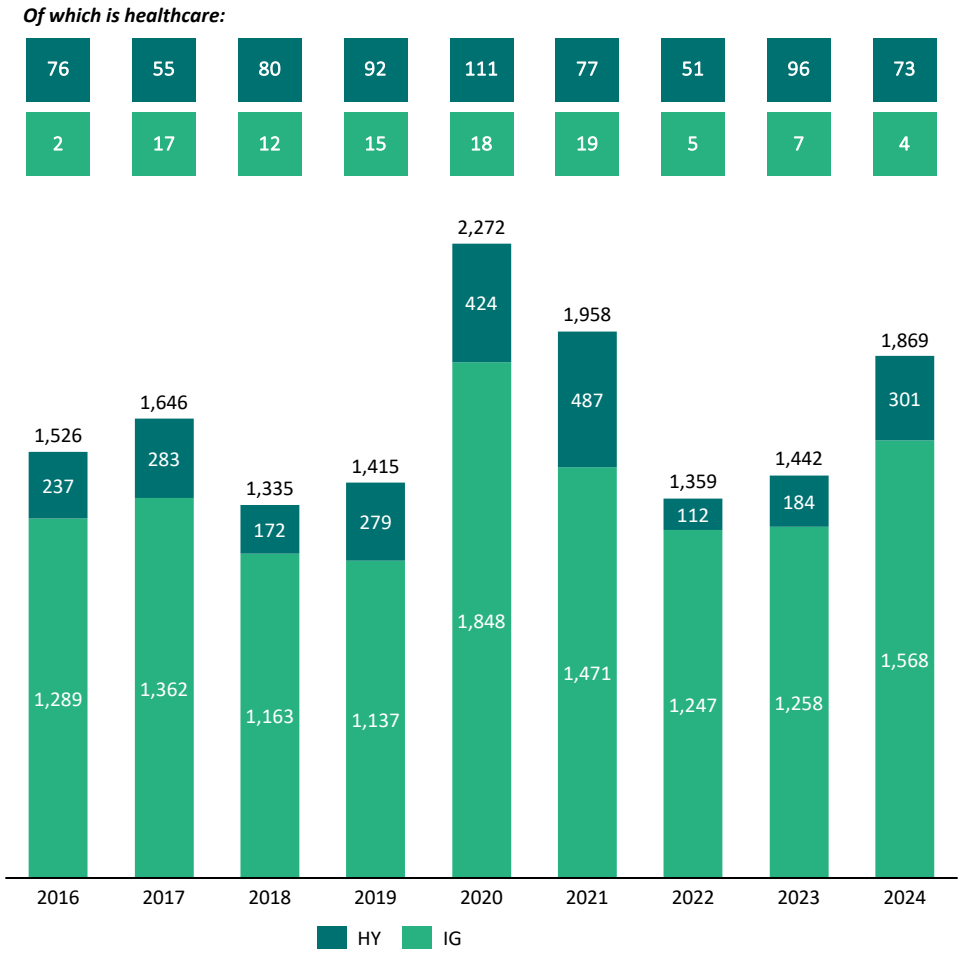


As a result, windows to access equity capital markets in 2025 are expected to be shorter than in late 2023–2024, and much shorter than in 2021

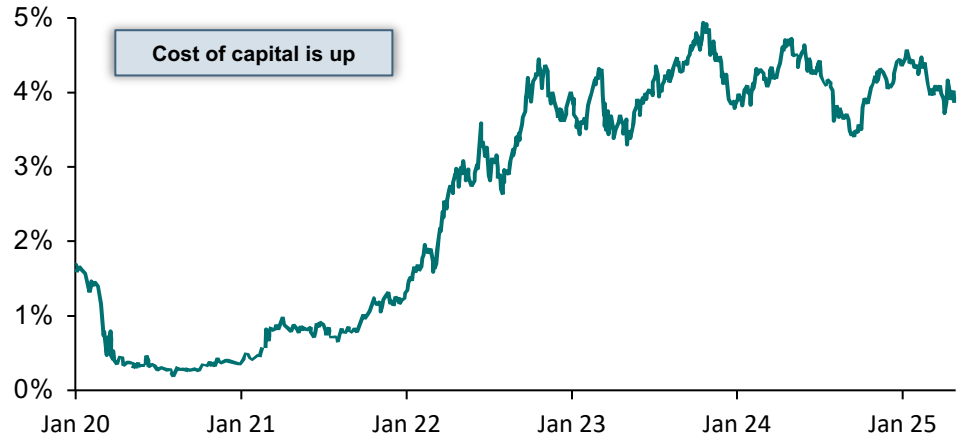
MOVE: ICE BofAML MOVE Index; VIX: CBOE Volatility Index
Sources: Bloomberg

Record corporate bond issuance from 2020 largely matures this year, adding to companies' capital needs alongside significant capex and R&D demands

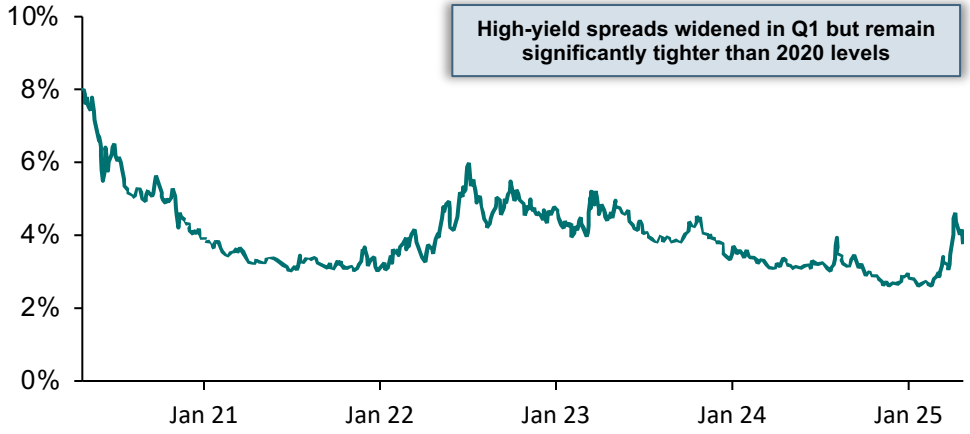
US Bond Issuance per Year (USDbn)



US 5-Year Treasury



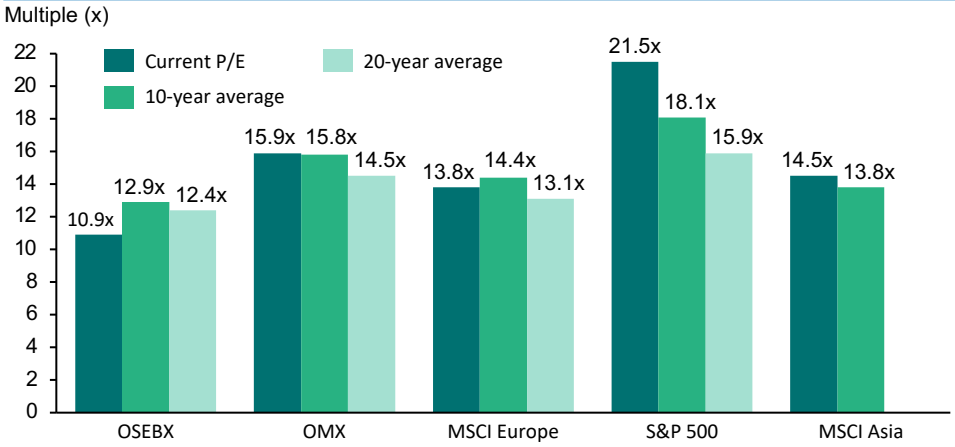
ICE BofA US High Yield Index

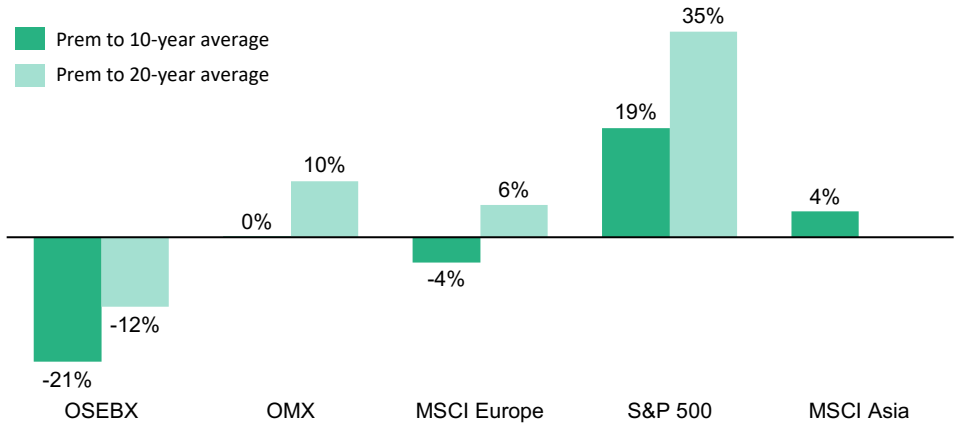


Sources: Bloomberg, SIMFA

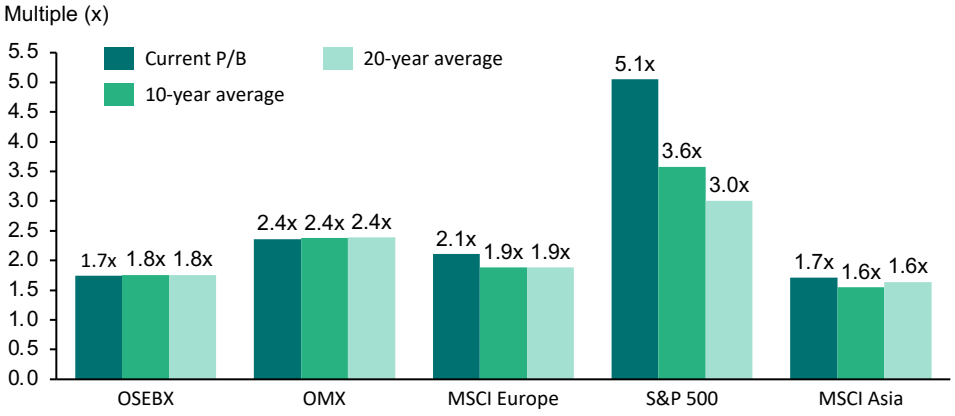
The US market maintains higher valuations compared to other emerging and established markets

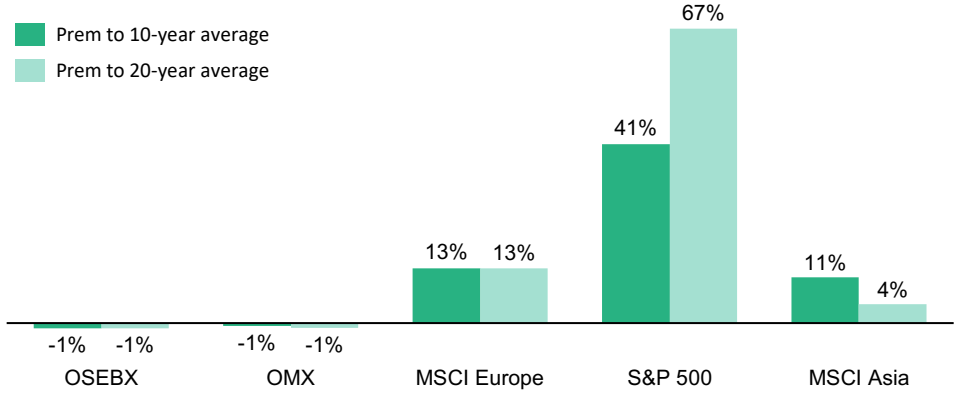
P/E Development and Current Premium over 10 and 20 Years





P/B Development and Current Premium over 10 and 20 Years





Sources: Bloomberg

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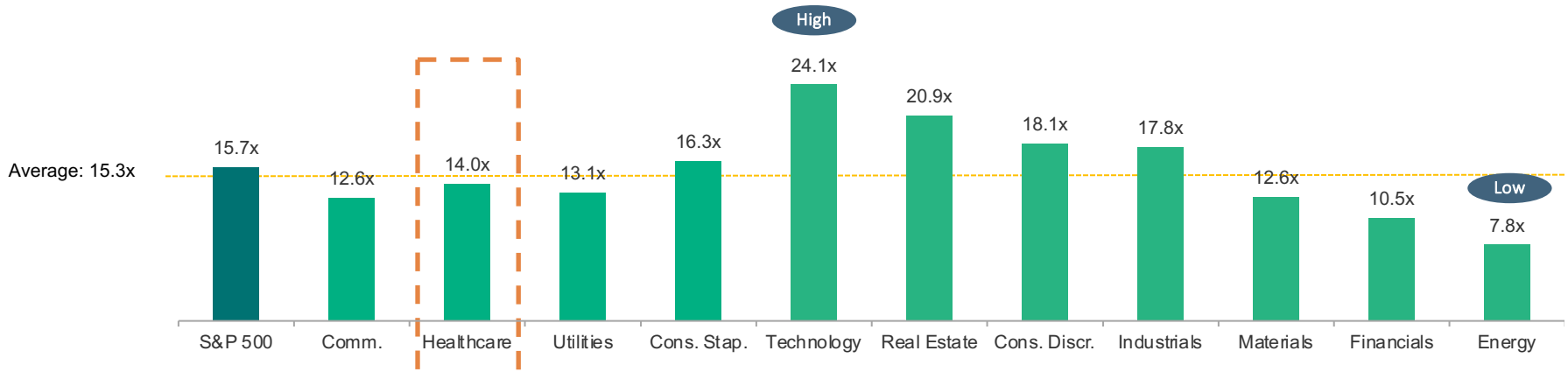
Healthcare currently sits slightly below average EV / EBITDA multiple at 14.0x, while technology and real estate are at the higher end of valuation

S&P 500 Sector EV / EBITDA and Performance



	S&P 500	Comm.	Healthcare	Utilities	Cons. Stap.	Technology	Real Estate	Cons. Discr.	Industrials	Materials	Financials	Energy
Weight	-	9.4%	11.4%	2.6%	6.4%	29.2%	2.3%	10.5%	8.4%	2.0%	14.4%	3.4%
Performance												
YTD	(3.8%)	(4.5%)	(3.7%)	5.8%	4.4%	(8.2%)	2.0%	(11.7%)	3.2%	0.8%	3.0%	(3.7%)
LTM	8.6%	11.4%	(7.4%)	12.5%	8.3%	12.3%	9.8%	10.4%	8.4%	(7.5%)	19.7%	(12.4%)
24M	37.4%	67.0%	0.2%	16.8%	11.5%	60.2%	12.4%	40.4%	37.0%	7.8%	54.6%	2.1%
Financials												
Annual Earnings Growth (CY 2025)	5.4%	7.2%	6.8%	6.6%	3.2%	12.4%	5.2%	4.3%	4.5%	4.3%	3.9%	(2.0%)
Earnings Growth (1Q 2025)	4.2%	6.5%	7.7%	5.2%	1.1%	11.4%	3.7%	2.8%	(0.9%)	2.3%	2.2%	0.2%
Sales Growth (5/9/2025)	4.8%	7.5%	8.8%	10.3%	0.3%	12.1%	4.7%	2.8%	(0.7%)	2.6%	3.0%	0.9%
Annual Earnings Growth (CY 2025)	11.3%	12.1%	18.2%	7.4%	1.3%	19.7%	1.9%	5.9%	11.9%	10.0%	7.4%	-
Earnings Growth (1Q 2025)	7.2%	20.7%	36.0%	10.1%	(8.0%)	14.8%	(0.6%)	1.6%	0.7%	(9.8%)	2.6%	(12.2%)
Earnings Growth (5/9/2025)	13.4%	29.1%	42.9%	13.7%	(6.7%)	17.4%	2.6%	8.2%	7.3%	(2.5%)	7.0%	(12.7%)
Net Profit Margin (1Q 2025)	11.3%	11.9%	7.4%	12.2%	6.0%	25.4%	35.0%	7.4%	10.2%	9.1%	13.4%	10.4%
Net Profit Margin (1Q 2024)	12.5%	14.2%	7.7%	13.2%	6.0%	26.5%	35.2%	8.8%	10.7%	9.0%	19.0%	7.7%

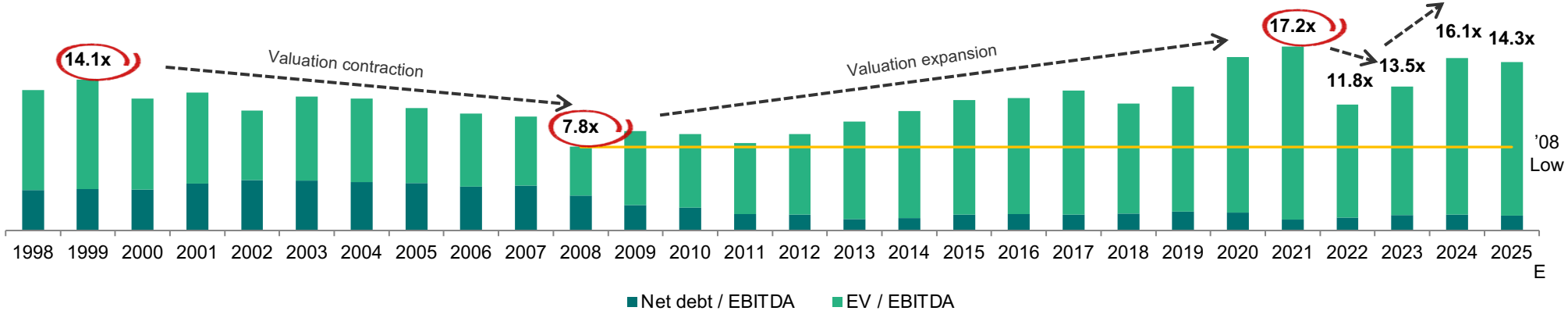
Note: EBITDA represents trailing 12 months EBITDA
Sources: Bloomberg, CapIQ, FactSet

The S&P 500 is facing valuation pressure amid signs of a market pullback, but stocks remain expensive

Median Valuation Measure for S&P 500 vs. 25+ year history (1998 - 2024)

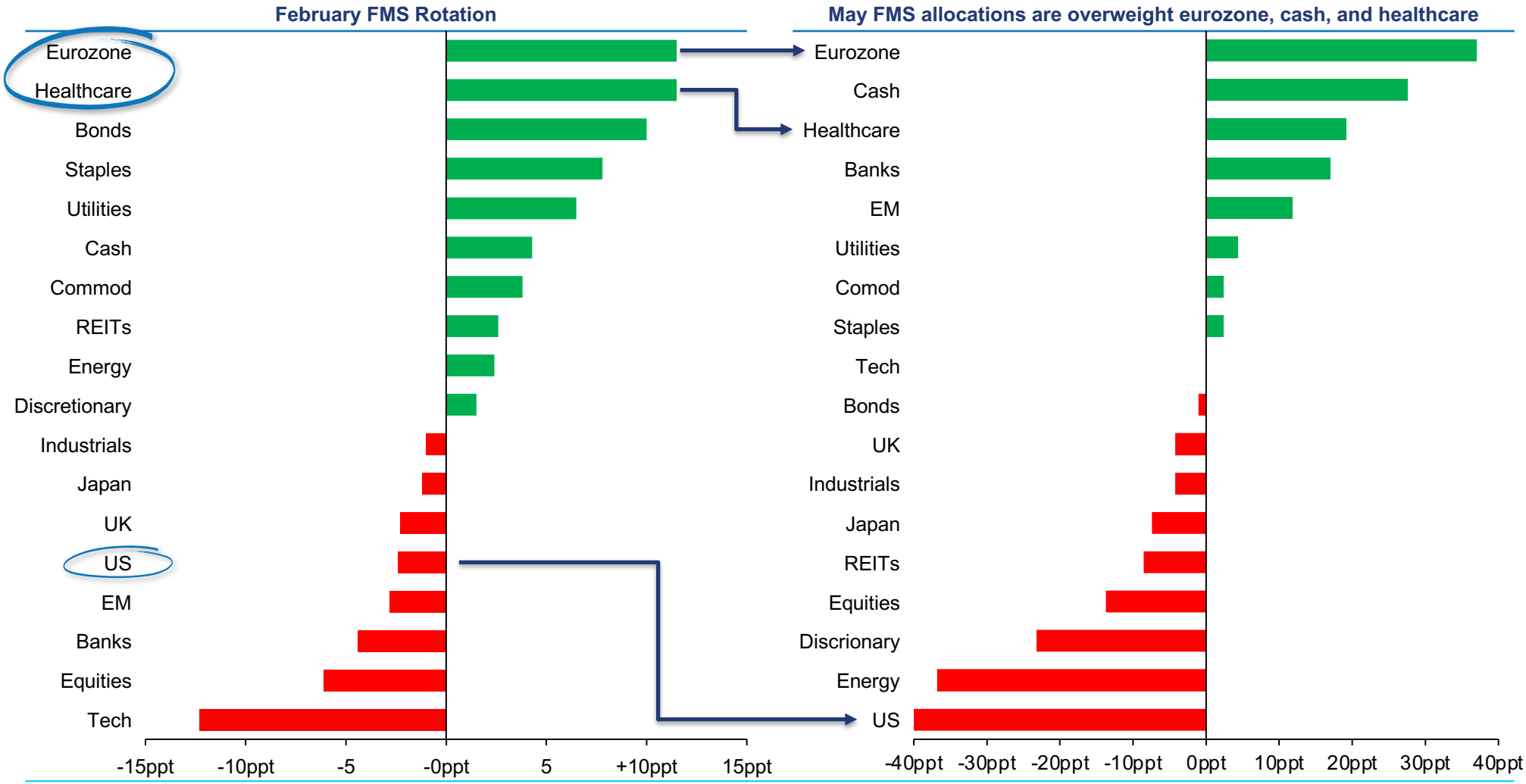
	Price / Fwd Earnings	Price / Fwd Sales	Price / Book	EV / Fwd Sales	EV / EBITDA	Market Cap / GDP
Current	21.8x	3.0x	5.1x	3.3x	16.1x	168%
Range since 1998	77%	98%	98%	98%	95%	98%
Peak	29.8x	3.2x	5.1x	3.3x	17.1x	181%
Date	6/30/1999	12/31/2021	9/30/2024	9/30/2024	12/31/2021	12/31/2021
Bottom	12.6x	0.8x	1.8x	1.2x	7.3x	50%
Date	9/30/2011	3/31/2009	3/31/2009	3/31/2009	3/31/2009	3/31/2009

S&P 500 Historical EV / EBITDA Valuation Trading Range (1998 - 2025E)



Note: EBITDA represents trailing 12 months EBITDA
Sources: Wall Street research, Bloomberg as of Q1 2025

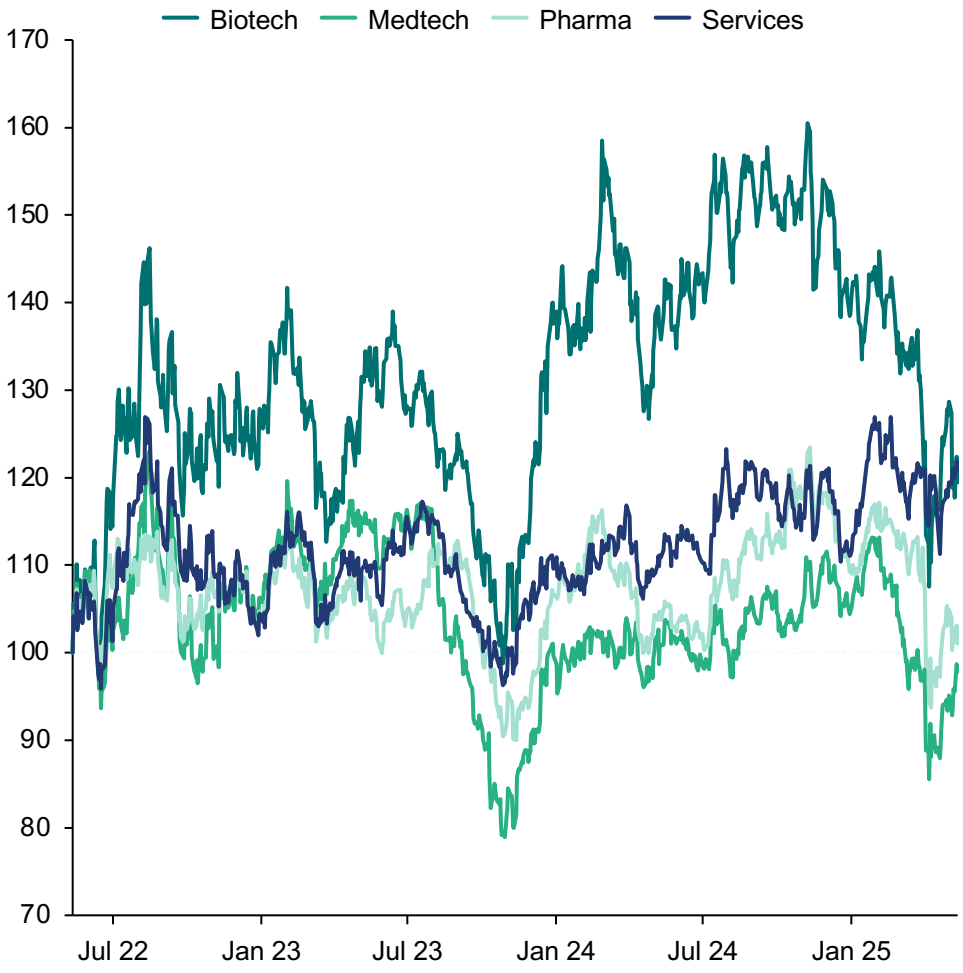
February marked a sharp shift as fund managers moved out of US equities and into European equities as well as healthcare stocks



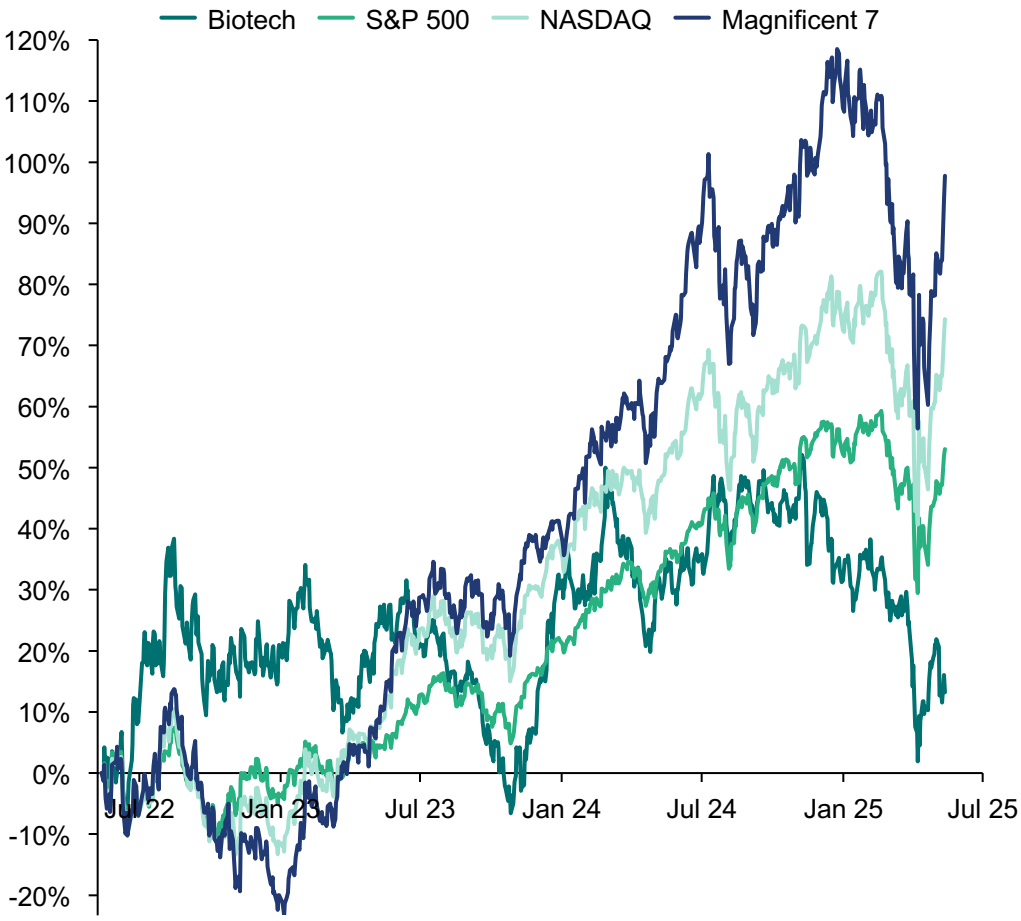
Sources: BoA Fund Manager Survey

Biotech has led healthcare sub-sectors in 3-year share price performance but significantly underperformed major indexes on total return

Indexed 3-Year Share Price Performance per Subsector



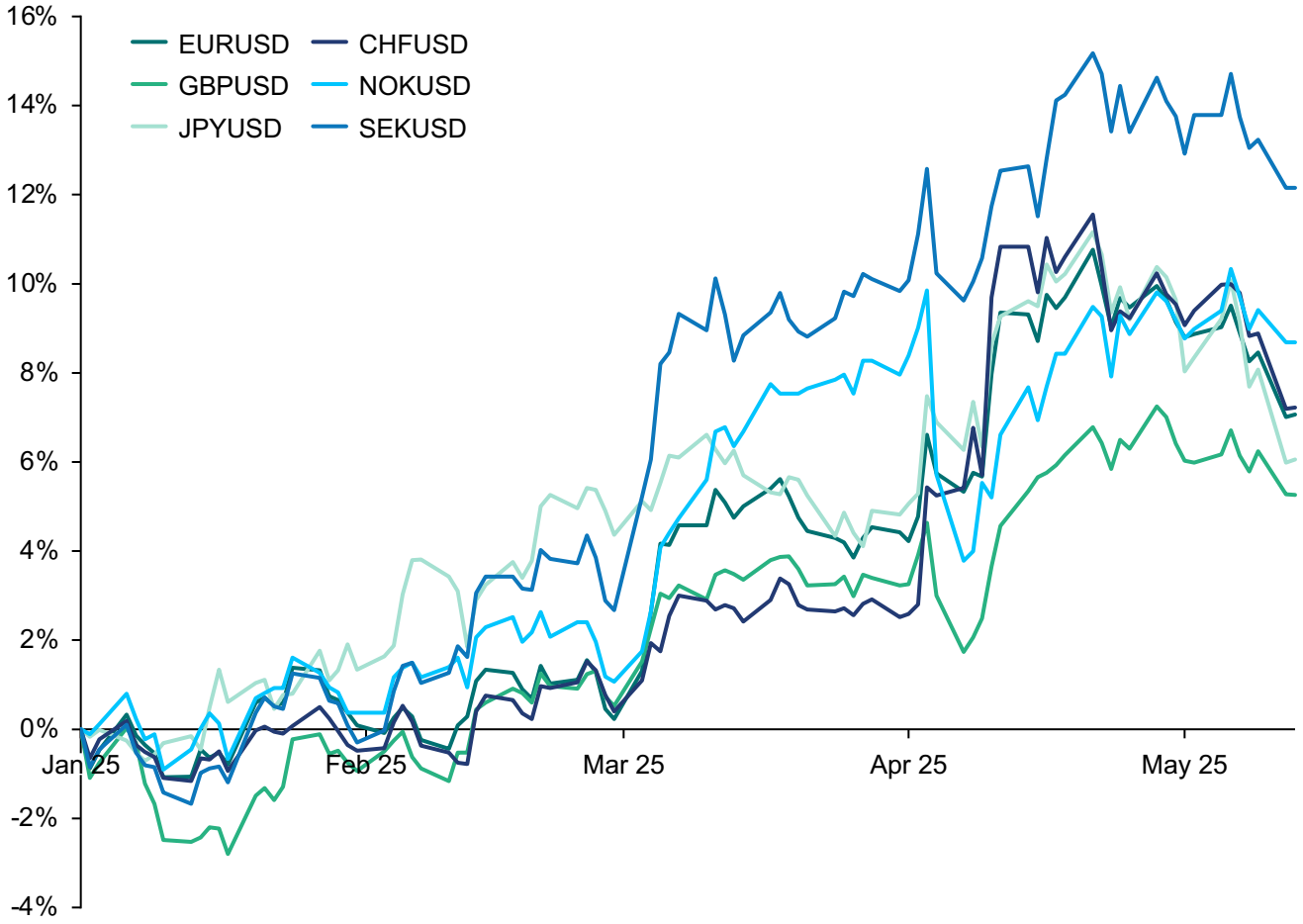
Total 3-Year Return: Biotech vs. Key Indexes



Subsector based on the following ETFS: SPDR S&P Biotech (XBI), SPDR S&P Health Care Equipment (XHE), SPDR S&P Health Care Equipment (XPH), SPDR S&P Health Care Services
Sources: LSEG, Bloomberg

Significant volatility in foreign exchange (FX) markets in the past year have continued into 2025

USD FX Accumulated Percent Change, YTD



Observations

- EURUSD experienced its strongest rally since 2009, driven by renewed optimism in Europe following German fiscal stimulus announcements
- The USD has weakened broadly due to shifting sentiment from US exceptionalism to concerns over soft economic data
- SEK was the top-performing major currency recently, supported by stronger Swedish data, upward inflation surprises, and expectations of a steady Riksbank policy rate
- NOK initially lagged SEK due to weak petroleum prices and structural pressures, but rebounded following upside inflation surprises and NOK rate repricing
- Investor flows show signs of repatriation out of the US into Europe and Scandinavia, influenced by political uncertainty and structural rebalancing
- Despite short-term corrections, structural headwinds for Scandi-FX remain, with continued pressure on NOK due to energy market dynamics and global uncertainty

Sources: DNB Carnegie research, Bloomberg

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Government healthcare agencies face significant structural changes, largely driven by policy goals that have led to mixed messaging and uncertainty

Policy Strategy	**Cutting Budgets**		**Enacting Tariffs**	**Development & Approval**	**Drug Pricing Policy Change**
Affected Entities	**Regulatory Oversight** **Regulatory oversight** of the FDA, with severe downstream effects for entities involved in any kind of clinical development	**R&D Organizations** **R&D organizations** such as the NIH and CDC, with downstream effects for the biopharma and medical device industry	**Manufacturing & Supply Chain** **Global manufacturing / US supply chain,** which will primarily impact pharmaceutical companies with downstream effects for contract organizations and hospitals	**Development Requirements** **Clinical development requirements** to be targeted in the administration's goal to prioritize efficiency	**Drug Price Negotiators** **Drug price negotiators,** including both manufacturers and Medicare, face an executive order that proposes significant changes to drug pricing
Expected Result / Intended Effect	**Loss of institutional knowledge and timelines** ▪ Multiple senior leaders resigned or laid off, creating significant concerns of loss of institutional knowledge and experience ▪ ~10,000 employees laid off across the HHS **Layoffs impacting key HHS agencies** ▪ FDA: ~3,500 employees (~19% of total workforce) ▪ CDC: ~2,000 (~18% of total workforce) ▪ NIH: ~1,200 (~9% of total workforce) **Budgetary changes implemented across the HHS** ▪ ~$20B (~40%) overall budget reduction proposed ▪ ~800 NIH grants placed on hold		**Planned tariffs to affect pharma, medical device, and medtech imports** ▪ Drug and device manufacturers: ~25-50% ▪ India (API and generics manufacturing): ~10% ▪ Mexico (device / raw materials): ~10-25% ▪ China (API, generics, and biologics manufacturing): ~30%	**Key hurdles in approval timelines and pricing negotiations** ▪ Animal testing requirement to be phased out ▪ Rare disease assets to receive special priority ▪ Generic and biosimilar path to market to be streamlined ▪ Expanded discussion around opportunities to integrate AI into reviews	**Increased pricing transparency and medication access** ▪ Medicaid "most favored nation" policy ▪ Improved pricing transparency by enhancing Medicare Drug Price Negotiation Program ▪ Targeting PBMs to promote efficiency in value chain ▪ Restrictions to 340B program ▪ Small molecules no longer subject to "pill penalty"

Introduced by executive order

A smaller, understaffed FDA can significantly impact regulatory timelines for the biopharma and medical device industry

Change	Responsibility of Replaced Party	Impact
New FDA commissioner	Dr. Martin Makary will lead the FDA as commissioner, replacing acting commissioner Dr. Sara Brenner	**Dr. Makary's comment addressed the following:** ▪ Streamlining approval of biosimilars, generics, and OTC to manage costs ▪ Utilizing RWD to expedite product review ▪ Examining food additives ▪ Maintaining clinical trial diversity
Departed regulatory leaders	**Office** / **Departing official** Center for Biologics Evaluation & Research — Peter Marks Center for Drug Evaluation and Research — Patricia Cavazzoni Center for Devices & Radiological Health — Janelle Barth Office of New Drugs — Peter Stein Office of the Chief Medical Officer — Hilary Marston	**Leadership shake-up at FDA raises concerns over regulatory delays and loss of institutional knowledge** ▪ Dr. Peter Marks, who fast-tracked COVID vaccine approval via Operation Warp Speed, is replaced by Dr. Vinay Prasad, a proponent of stricter vaccine oversight ▪ 207 biotech innovators claim in a letter to the Senate HELP Committee encourages the FDA to rehire leaders and preserve knowledge ▪ Small, clinical stage biotech companies express particular concern that the loss in experience will cause review delays, threatening future funding goals
Layoffs to FDA project managers and support staff	**Liaison with biotechnology, pharmaceutical, and medical device manufacturers** ▪ Discussing and navigating clinical holds on trials ▪ Supporting review staff ▪ Maintaining access to scientific literature	**Key regulatory deadlines already missed, with significant delays forecasted** ▪ Novavax COVID-19 vaccine & GSK's Nucala approval decision deadlines missed ▪ Biotech CEOs confirming delay in scheduling routine meetings and lack of senior team members to assist with clinical development challenges ▪ However, delays at Daré, Vanda, and Stealth appear more tied to company or drug issues, not FDA slowdowns, per STAT's Adam Feuerstein
Layoffs to international support staff	**Secure infrastructure to support reviewer/inspector international travel** ▪ Travel support team to coordinate flights and logistics ▪ On-site support team to hire translators to facilitate inspection	**Limited travel to CDMO sites indicates critical delays to site inspections and subsequent drug approvals** ▪ Current inspection rates declined due to pandemic related travel restrictions and remain below pre-pandemic levels, slowing inspector hiring and retention ▪ While ~20 of 60 travel staff will be reinstated, inspectors will likely absorb many administrative tasks, predicted to negatively impact morale and retention

Sources: *Endpoints*: "CDMOs anticipate inspection bottlenecks after mass FDA firings"; *STAT:* "Inside US health agencies, workers confront chaos and questions as operations come unglued"; Leaked budget document outlines how Kennedy may cut up HHS to build new AHA"; *USAToday:* "Charts show where tariffs stand now: See percentages, which countries are hit hardest"

NIH and CDC funding cuts have stalled research, pushing scientists to search for new jobs and raising concerns over a slowdown in US innovation

Change	Responsibility of Replaced Party	Impact
New NIH and CDC leadership	▪ Dr. Jay Bhattacharya to assume leadership of the NIH, replacing Dr. Monica Bertagnolli ▪ Dr. Susan Monarez to assume leadership of CDC, replacing Dr. Rochelle Walensky	**Dr. Bhattacharya's policies are broadly in line with those of RFK Jr.'s** ▪ Core goals include reducing focus on infectious disease and shifting attention to chronic diseases ▪ His encouraging of research on the link between vaccines and autism has drawn criticism from the scientific community **Dr. Monarez's previous positions contrast with RFK Jr.'s policy goals** ▪ She has spoken numerous times about equitable access to health care innovation, such as digital/AI capabilities
Decreased funding to select NIH groups	**Drive critical research affecting both population health and drug development** ▪ National Institute on Minority Health and Health Disparities ▪ National Institute of Allergy and Infectious Diseases ▪ National Center for Advancing Translational Sciences ▪ National Institute of Nursing Research	**Serious concerns that the US may fall behind China in research and innovation** ▪ Halting research funding, notably for translational science, suggests drug development and innovation will slow ▪ Meanwhile, China continues producing cutting-edge research push ▪ Chinese biotechs are increasingly outlicensing technology and assets to US-based biopharma companies ▪ Many consider Chinese dominance of the biotech industry to be one of the most serious national security threats
Layoffs and terminated grants	**Drive core scientific research** ▪ ~1,200 researchers laid off from NIH **Lead specialized research in infectious disease** ▪ HIV/AIDS (28.7% of grants terminated) ▪ COVID-19 (17.1% of grants terminated)	**High proportion of young scientists (~75-80%) considering leaving the US due to terminated grants and researcher layoffs** ▪ Of ~700 US-based early-career researches, ~550 indicated they were considering leaving the US ▪ Of ~350 PhD students, ~260 indicated they are considering leaving the US
Shutdown of key CDC groups	**Maintain critical response units for public health emergencies** ▪ National Institute of Occupational Safety and Health ▪ Global Health Center	**CDC group shutdowns and layoffs creating concern that the agency may not respond adequately in case of a public health crisis** ▪ Lack of staff and support for emergency preparedness can lead to a slow emergency response ▪ Leaders claim it is less expensive to stop health threats internationally rather than wait for them to arrive in the US

Sources: *Nature*: "How Trump 2.0 is slashing NIH-backed research — in charts"; 75% of US scientists who answered Nature poll consider leaving; *STAT*: "Trump budget draft proposes NIH consolidation and 40% spending cut", "At CDC, Trump administration's job cuts wipe out wide array of specialists", "The CDC's critical occupational safety institute has been virtually wiped out", "CDC officials plan for the agency's splintering, but questions remain"

Pharmaceutical tariffs and broader foreign trade tariffs could pressure drug manufacturers to invest in US-based manufacturing

Change	Goal of Levied Tariff	Impact
Pharma expects tariff of ~25-50%	**Incentivize large pharmaceutical players to move manufacturing back into the US**	**Pharma manufacturers to face tariff-related financial headwinds** ▪ J&J expects a ~$400.0M increase in indirect costs, while Merck and Pfizer anticipate ~$200.0M and ~$150.0M in expenses respectively ▪ Analysts anticipate a ~25-50% tariff will affect pharma EPS by ~4-5% and claim companies are importing as much product as possible ahead of potential tariffs ▪ Analysts further indicate pharma may respond by raising drug prices, but not enough to fully offset the financial impact of tariffs ▪ J&J, Eli Lilly, Roche, Regeneron, and Novartis plan to invest ~$150.0B in US manufacturing over the next five years, possibly to mitigate long-term tariff risks ▪ Deprioritizing R&D for manufacturing in the near term is expected to exacerbate drug shortages, creating accessibility issues for patients
US-imposed foreign trade tariffs, ranging from ~10% (standard) to ~50% (China-specific)	**Rectify perceived "trade imbalances", thereby maintaining a protectionist trade strategy**	**Tariff on foreign countries with high manufacturing activity, generally China, Mexico, and Europe, is expected to impact top medical device companies** ▪ Initially as high as ~145%, US tariffs on Chinese goods decreased to 30% following a temporary rollback of tariffs for 90 days starting May 14, 2025 ▪ Medical device companies still face steep tariffs (~30% in China, ~25% in Mexico, ~20% in Europe), though expected 2025 impact has eased; CFO commentary from Q1 2025 earnings calls reflected greater concern prior to the recent China-US deal: - Zimmer Biomet CFO had expected "~$60-80M headwind to operating profit" - GE Healthcare CFO had expected a "tariff impact of ~$500M" for the year - Intuitive CFO had projected a "~4.5 percentage point headwind to earnings per share" ▪ A recent Association for Supply Chain Management indicated ~65% of surveyed supply-chain professionals planned to pass increased costs to customers - For medical devices, policy experts estimate higher costs for hospitals and increased prices for consumers because of this supply chain disruption

Sources: *BioPharmaDive*: "Pharma bosses face down investor angst on tariffs, HHS chaos"; *Endpoints*: "Biotechs start to disclose tariff exposure with US trade inquiry underway"; *FierceBiotech*: "Novo Holdings dials back investment as Trump stymies economic forecasters", Market volatility compounds 'already challenging' year for biotech IPOs; *Medical Device Network:* "Q1 Earnings News Reports"; *S&P*: "What Looming Tariffs Could Mean For US Corporates";

To prioritize efficiency and champion innovation, the new administration is aiming to remove development & commercial barriers in the biopharma industry

Change	Goal in Addressing Barrier	Impact
Removing animal testing prerequisite	**Offer flexible preclinical development strategies to manufacturers by adopting AI-driven models and human-relevant in vitro systems**	**Policy favors AI / computational modeling companies** ▪ Schrodinger CEO Ramy Farid praised the change, claiming computational solutions will play a vital role in reducing the use of animal models ▪ Infinimmune CEO Wyatt McDonnell highlighted the value of AI models that train exclusively on human antibody data, noting better predictive capabilities when models focus on human biology
Addressing slow, data-sparse rare disease development	**Accelerate rare disease drug development and approval by coordinating CDER and CBER to shift attention to rare disease activities**	**Rare disease innovation receiving specific attention from the FDA** ▪ FDA Commissioner Dr. Marty Makary proposing expedited, mechanism-based rare disease pathway to approve drugs even without RCT data ▪ Makary proposes a post-approval surveillance system to monitor patients receiving treatment, tracking progress and collecting data in real time ▪ Former commissioner Dr. Bob Califf stated rare disease support already exists, citing accelerated approval, expanded access, and Right to Try Act programs
Fixing a slow approval timeline for generics and biosimilars	**Streamline approval pathway for generics and biosimilars, enabling greater access to non-branded medications and providing additional treatment options for patients**	**Generics and biosimilars manufacturers to benefit from reduced time to receive FDA approval** ▪ Pharmaceutical companies will likely be affected, with faster time to market for generics placing additional pressure on branded drug market share ▪ Despite this change, the FDA, including the office of Generic Drug Policy, is still navigating next steps after a significant reduction in force, suggesting these changes may take time to fully implement even if approved by Congress
Modernizing the FDA's capabilities with AI	**Leverage cutting-edge AI technologies to streamline regulatory workflows, in line with the FDA's broader push to accelerate drug approval timelines**	**New positions to champion use of AI and increased discussion with top AI companies** ▪ Jeremy Walsh was hired to be the FDA's first ever AI officer, tasked with speeding scientific reviews and rolling out a generative AI platform across FDA centers ▪ FDA is reportedly in active discussions with OpenAI on a potential collaboration, tentatively called "cderGPT," which is speculated to support regulatory efficiency within the Center for Drug Evaluation and Research (CDER)

Sources: *BioPharmaDive:* "FDA, aiming to speed scientific reviews, names chief AI officer"; *BioSpace:* "Makary Discusses Expedited Rare Disease Approvals Pathway, 'Public Distrust' in New Interview"; *Contract Pharma*: "Insight on FDA's Plan to Phase Out Animal Testing for mAbs and Other Drugs"; *Schrodinger:* "Schrödinger's Statement Regarding FDA Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs"; *STAT*: "Why the closure of an FDA office may impact generics manufacturers — and everyday Americans"; *Wired:* "OpenAI and the FDA Are Holding Talks About Using AI In Drug Evaluation"

While executive orders look to reduce drug prices and increase transparency, actual pricing impact remains unclear

Change	Goal in Addressing Barrier	Expected Impact to Drug Price	Impact
Enact "most favored nation" policy for Medicare / Medicaid	**Rectify the perceived imbalance in drug pricing faced by U.S. patients (vs. patients in other countries)**	↓	**Medicare / Medicaid to communicate lower, "most-favored-nation" price targets to drug manufacturers** ▪ Drug prices paid by Medicare / Medicaid could be capped at the lowest price available in other developed countries, easing state budget pressures; direct-to-consumer programs at MFN prices may also allow patients to bypass intermediaries like PBMs ▪ However, manufacturers may respond to reduced reimbursement rates by pulling drugs from Medicare / Medicaid or limiting supply, risking higher costs and reduced access for patients
Remove middlemen in the pharma value chain	**Create a competitive, efficient value chain that fosters more direct pricing negotiations**	↓	**Enforced transparency requirements for pharmaceutical benefit managers (PBMs), notably around payment disclosures** ▪ Trump administration to target PBMs that pay consulting firms contracted by large employers to help negotiate optimal pricing ▪ While a 2020 law requires payments that brokers / consultants receive from PBMs and insurers to be disclosed, the White House maintains this rule has not been enforced
Restrict 340B discounts to hospitals	**Ensure discount savings from the 340B program are passed onto patients**	↓	**Heavily restricted 340B program-related discounts, preventing hospitals from accumulating profits by providing eligible drugs to low-income patients** ▪ CMS lowered the Medicare payment rate for 340B drugs in 2022, triggering a lawsuit from hospitals claiming the rate was lowered unlawfully ▪ While these hospitals won, the Supreme Court also found that had the hospitals' drug acquisition costs been surveyed, the lower rate would have been lawful ▪ The executive order mandates this survey, after which rates will be reconsidered and adjusted "to align Medicare payment with the cost of drug acquisition"
Enhance drug pricing transparency	**Encourage pharmaceutical companies to engage in more transparent pricing practices**	↓	**Optimized Medicare Drug Price Negotiation Program (MDPN) to improve pricing transparency** ▪ Trump administration hopes to improve the MDPN, created under the IRA, and "eclipse the 22% in savings" achieved by Medicare in the program's first year ▪ Executive order advises RFK Jr. to find ways to improve program's transparency and reduce undefined "negative effects" of pharmaceutical innovation
Eliminate IRA-mandated "pill penalty"	**Extend the negotiation timeline for small molecule drugs to 13, enhancing market viability and encouraging R&D investment**	↑	**Small molecule manufacturers expected to benefit from improved revenue in late-stage commercial lifecycle** ▪ The Center for Pharmacoeconomics (CPE) supported the move, estimating that the pill penalty would have led to 79 fewer small molecules approved over the next 20 years ▪ Small molecule drugs would be shielded from Medicare price negotiations until later in their lifecycle, prolonging higher costs for patients

Sources: *American Hospital Association*: "AHA Statement on Most Favored Nation Model Interim Final Rule"; *FDA.gov; Federal Register*: "Most Favored National Model"; *Forbes*: "Trump Executive Order Addressing 'Pill Penalty' In Drug Pricing Law Faces Uphill Battle"; *ThePharmaLetter*: "Trump revives most favored nation plan, but only for Medicaid"; *WhiteHouse.gov*

Ongoing policy shifts have triggered a more cautious investment environment, with institutional investors slowing activity and pharma more selective on deal making

- **Reduction in FDA resources**
- **Cuts to NIH / CDC**
- **Uncertainty in pharma-specific tariffs**
- **Disruptive changes to regulatory review routes**
- **Unclear drug pricing changes**

Life science investors hit pause and reassess strategy amid sweeping policy shifts

Life-science focused investors

Ongoing volatility has led life science investors to scale back investments

- Funds are slowing investments, citing trade disruption & shifting policy as drivers of uncertainty

Big pharma

Big pharma CEOs acknowledge market uncertainty but show willingness to invest in the right deals

- Early sentiments on the new administration reflected optimism, citing a more "deal-friendly" environment
- Threat of tariffs, among other policy changes, has challenged this notion
- Multiple leaders have cited cautious, disciplined approaches to M&A as core to their 2025 mandate
- Several CEOs mentioned looking to innovation coming out of China

*Bellevue Asset Management Fund Manager Christian Koch recently claimed portfolio companies were trying to find **alternative ways to extend their cash runways***

*Novo Holdings CEO Kasim Kutay had planned to **exit some of the assets this year**, but those actions could now be **pushed to 2026…** also telling investors, **"We will slow investment activities… we're in the midst of uncharted waters."***

*BMS CEO Chris Boerner claims "**Business development is our top capital allocation priority,**", implementing a cost-savings initiative to be "more engaged on business development"*

*Pfizer CEO Albert Bourla caveated that his team needs to "be disciplined", but reinforced his M&A strategy to "**buy when prices are low**"*

*Merck & Co. CEO Rob Davis mentioned "business development [is] a "top priority", but cited market conditions "**make it more complex to get things done**"*

*GSK CEO Emma Walmsley, while agreeing that potential tariffs will impact dealmaking, spoke **optimistically of GSK's dealmaking potential***

Sources: *BioPharmaDive*: "Novo Holdings dials back investment as Trump stymies economic forecasters"; into deeper slump; *BioSpace*: "Novartis Strikes on M&A, Leading a Line of Big Pharmas With Cash to Spend"; *Bloomberg*: "Tariff War Draws Investment Warning From $160 Billion Novo Fund"; FierceBiotech: *"M&A remains 'top priority' for Big Pharmas in the face of tariff threat"*, *Reuters*: "Trump health policy uncertainty sends biotech sector into deeper slump"

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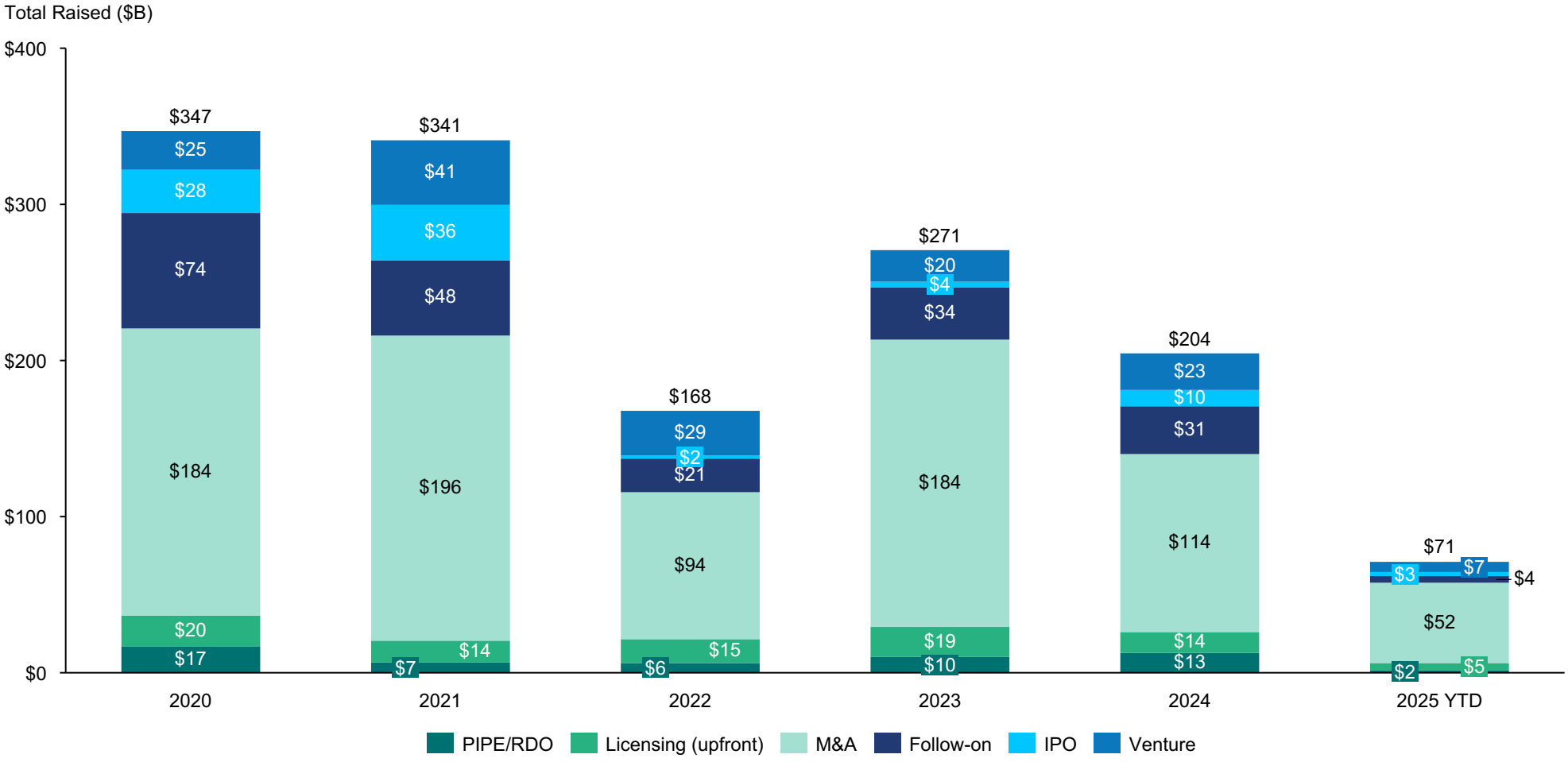
Healthcare dealmaking started the year on a promising note but activity has since stalled amidst tariff discussions, budget cuts, and unresolved regulatory questions

Total Healthcare Proceeds (2020 - 2025 YTD)[1]

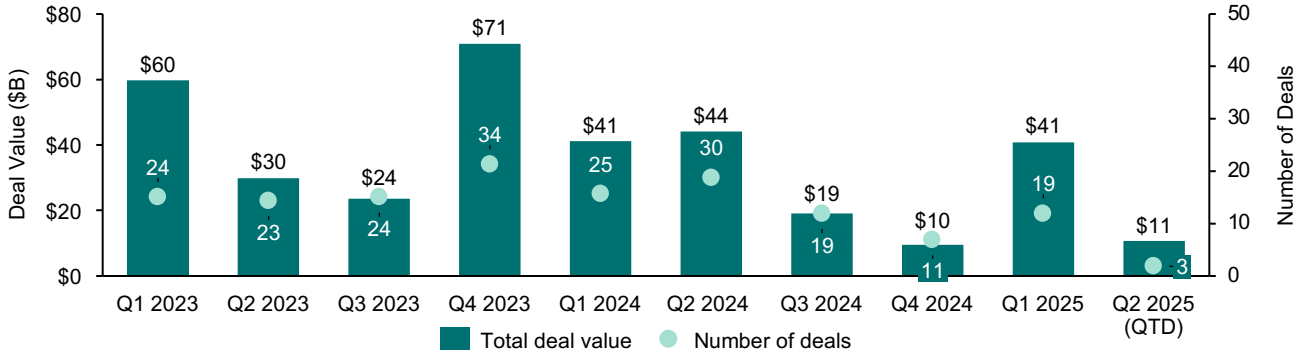


1. As of 5/9/2025
Sources: CapIQ, BiomedTracker

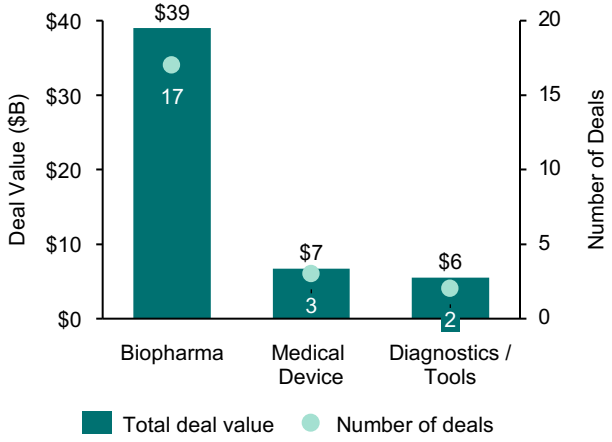
M&A deal value rebounded from the lows in H2 2024 as acquirors conducted fewer but larger size deals targeting commercial-stage companies

US & Europe Healthcare M&A Deal Breakdown[1]

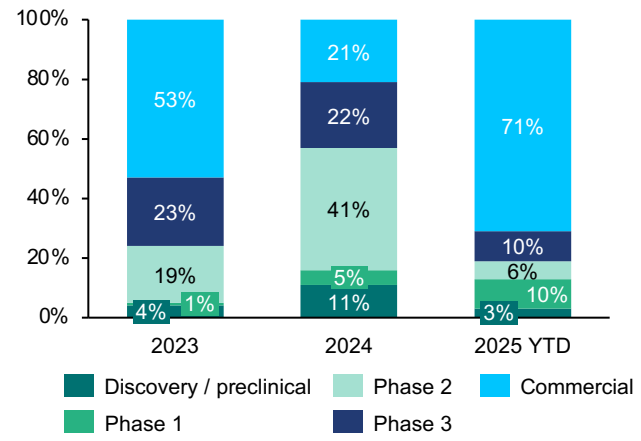
M&A Deals by Quarter (2023 - YTD)



M&A Deals by Sector 2025 YTD



Biopharma M&A by PoD (Based on Deal Value)



Key Takeaways

Q1 2025 M&A value increased from H2 2024 despite fewer transactions

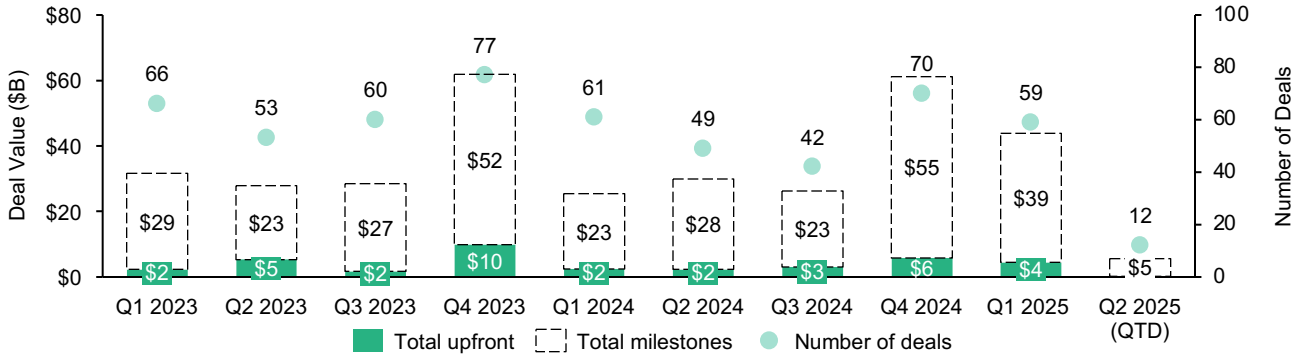
- Deal volume in Q1 2025 was tied for the second worst quarter over the past two years; however, deal value topped Q3 and Q4 2024 combined
- Median M&A deal size in Q1 2025 was $1.0B, the highest in two years, driven by acquirors spending more on mature companies
- Increased proportion of commercial stage deals, likely driven by:
  - Revenue loss from upcoming patent cliffs
  - Uncertain regulatory timelines
- Global pharma companies increasingly engaging with Chinese firms to access innovative therapies and potentially at lower valuations, benefiting from China's expedited trial processes
  - For example, BioNTech's acquisition of Biotheus, a clinical-stage oncology company developing bispecific antibody candidates, for $800M and up to $150M in milestones
- M&A has had a good start in Q2 with the recent acquisitions of Regulus Therapeutics ($1.7B) and SpringWorks Therapeutics ($3.9B)

1. As of 5/9/2025
Sources: BiomedTracker

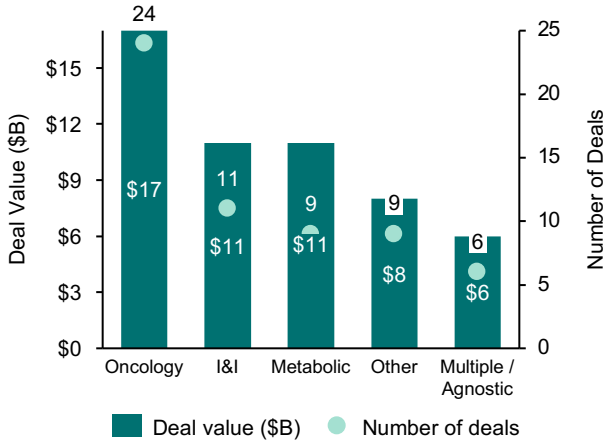
On the licensing front, discovery / preclinical deals have garnered attention albeit at lower upfront commitments

US & Europe Healthcare Licensing Breakdown[1]

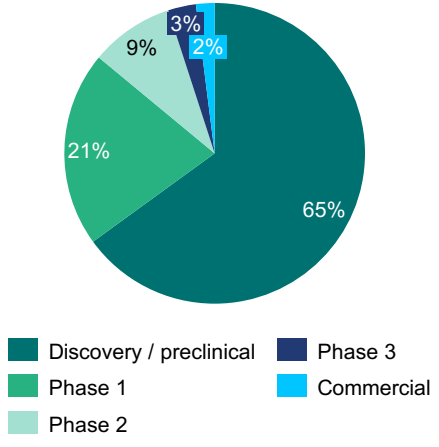
Licensing Deals by Quarter (2023 - YTD)



Biopharma Licensing Deals by Indication 2025 YTD



Biopharma Licensing by PoD (Based on Deal Value) 2025 YTD



Key Takeaways

Median upfront payments in Q1 hit their lowest levels in two years ($21.0M) as licensees wrote smaller checks focusing on earlier-stage opportunities

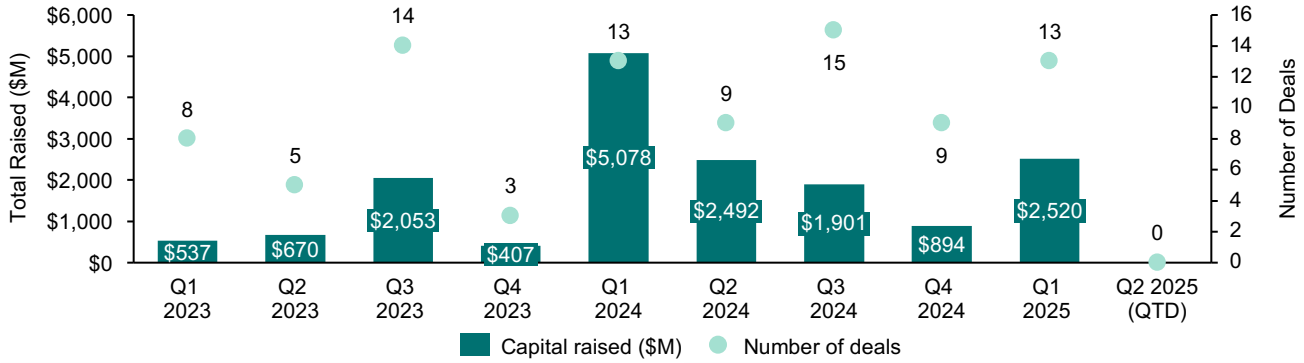
- Licensing deals are primarily for biopharma assets / programs
- Increase in biopharma licensing for discovery / preclinical assets (up ~20% YoY), potentially due to:
  - Preference for licensing vs. full M&A for risky programs
  - Reduced upfront cost and financial risk
  - Rebuilding pipelines
  - Increased cross-border opportunities
- Median upfront payments dropped to 3% of median deal value (vs. 6% in 2024) across all deals since Q1 saw more earlier-stage transactions
- The obesity space continues to garner interest as licensing deals have already outperformed 2024 ($11.0B YTD compared to $9.0B in 2024)
  - Performance was driven by two deals around amylin assets (Zealand's out-license of petrelintide to Roche for $5.2B and Gubra's out-license of GUB014295 to AbbVie for $2.2B)

1. As of 5/9/2025
Sources: BiomedTracker

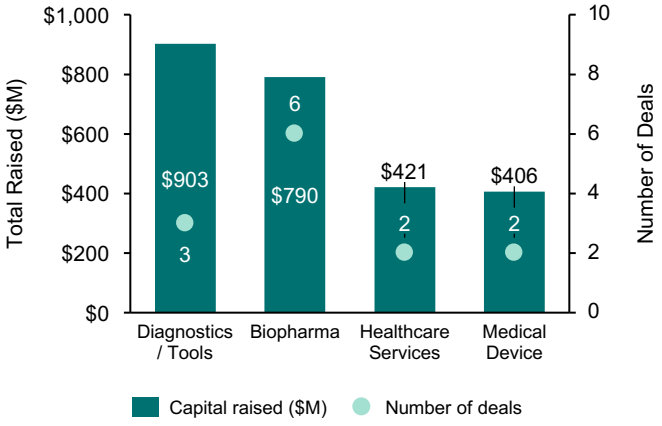
The year opened with a promising volume of IPOs, however, activity quickly stalled due to challenging headwinds for the healthcare sector and equity markets broadly

US & Europe Healthcare IPO Breakdown

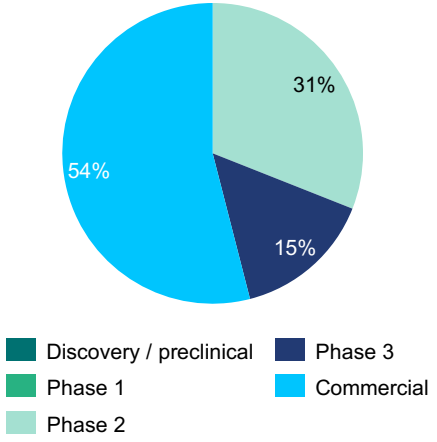
IPOs by Quarter (2023 - YTD)



IPOs by Sector 2025 YTD



IPOs by PoD (Based on Deal Volume) 2025 YTD



Key Takeaways

IPO proceeds observed an uptick from the lows in the back half of 2024 but activity has since stalled in the face of turbulent equity markets

- First two months started out strong with 9 out of the 13 IPOs in 2025 pricing in the first two months, but activity has since dropped off
- IPOs have struggled this year with 7 out of 13 companies currently trading below their issue price[1]
- The average and median performance YTD for IPOs has been poor at -10.1% and -17.6%[1], respectively
- Diagnostics / tools have led the way by deal value thanks to Asker Healthcare's $888.1M IPO on the Nasdaq Stockholm, making it the largest healthcare IPO YTD
- 54% of IPOs YTD have been for commercial-stage companies (a ~45% increase compared to 2024), demonstrating that public markets investors are more risk adverse and that it's a challenging environment for clinical companies to list

1. As of 5/9/2025
2. Micro-IPO is defined as an IPO that does not involve a bulge-bracket bank and proceeds raised being ≤ $100M

Sources: CapIQ

Healthcare IPOs that have priced in 2025 have underperformed with only 3 companies trading above issuance

Major US & Europe Healthcare IPOs YTD

Filing Date	Listing Date	Process Length	Company	Sector	TA	POD	Exchange	City (State)	Total Proceeds	IPO Price	Offering Range	IPO price relative to offering range	One Day Performance	Performance To-Date[1]
3/5/25	3/27/25	3 weeks	ASKER	Diagnostics /Tools	Numerous	Commercial	Nasdaq Stockholm	Danderyd	$888.1	$7	NA	NA	19.6%	31.3%
2/10/25	3/5/25	3 weeks	kestra MEDICAL TECHNOLOGIES	Medical Device	Cardio-vascular	Commercial	Nasdaq	Kirkland (WA)	$202.0	$17	$14-16	Above	28.5%	33.4%
1/23/25	2/12/25	3 weeks	aardvark therapeutics	Biopharma	Metabolic	Phase 3	Nasdaq	San Deigo (CA)	$94.2	$16	$16-18	Within	-10.6%	-34.9%
1/17/25	2/6/25	3 weeks	sionna	Biopharma	Respiratory	Phase 2	Nasdaq	Waltham (MA)	$190.6	$18	$16-18	Within	38.9%	-31.6%
1/10/25	1/30/25	3 weeks	Metsera	Biopharma	Metabolic	Phase 2	Nasdaq	New York (NY)	$275.0	$18	$15-17	Above	47.2%	32.6%
1/7/25	1/30/25	3 weeks	m22 THERAPEUTICS	Biopharma	Numerous	Phase 2	Nasdaq	San Francisco (CA)	$140.0	$16	$15-17	Within	-0.3%	-39.9%
1/6/25	1/29/25	3 weeks	Beta Bionics	Medical Device	Metabolic	Commercial	Nasdaq	Irvine (CA)	$204.0	$17	$16-17	Within	39.0%	-17.9%

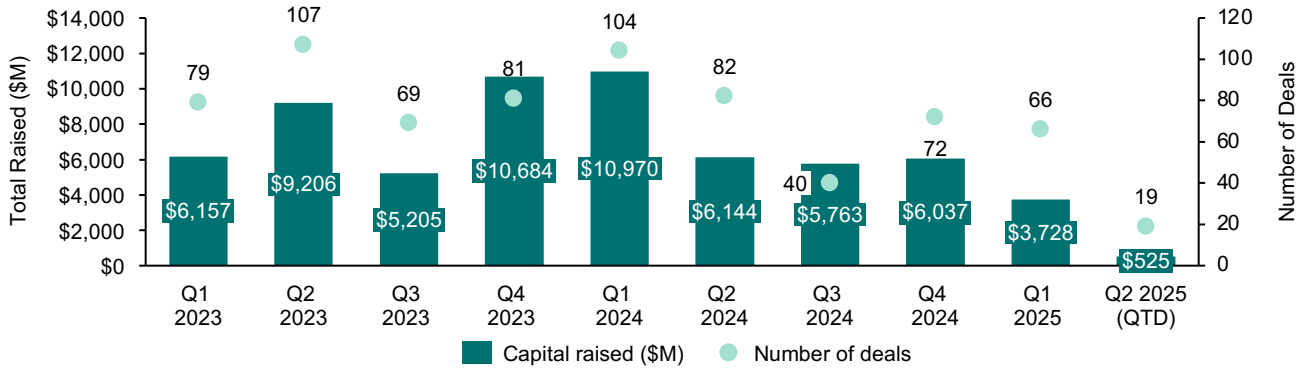
Average	23.2%	-3.9%
Median	28.5%	-7.9%

1. As of 5/9/25
Sources: CapIQ

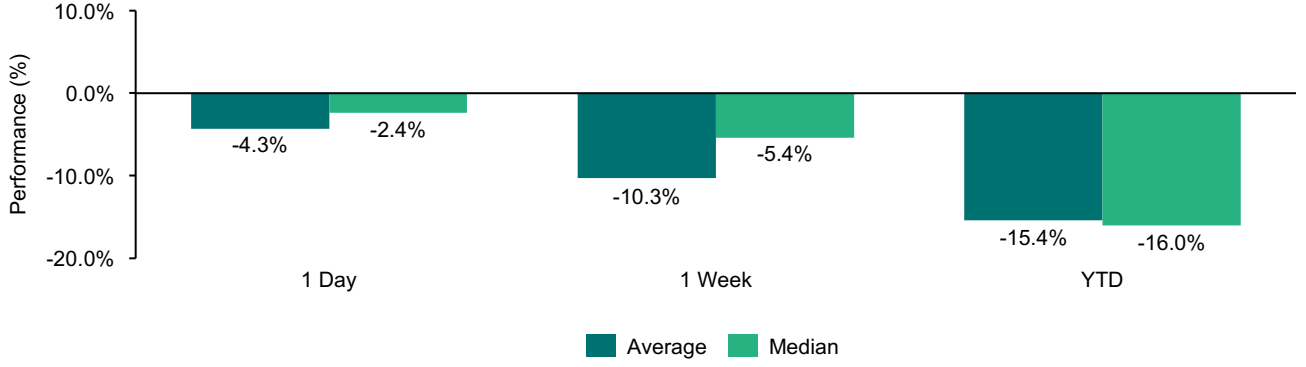
Follow-on proceeds raised in Q1 2025 dropped to its lowest levels in over two years

US & Europe Healthcare Follow-On Breakdown

Follow-Ons by Quarter (2023 - YTD)



After Market Performance of 2025 Follow-Ons



Key Takeaways

Follow-ons in Q1 2025 was the slowest it's been on record for two years by aggregate proceeds raised as companies struggled to raise capital

- Amount raised in Q1 2025 dropped 38% from Q4 2024 as challenging public market conditions and depressed valuations have impeded companies' ability to raise capital
- Companies have also struggled to raise sizeable rounds, making burn efficiency and maximizing cash runway key to navigating this slowdown
  - The average raise in Q1 2025 was $56.5M (compared to an average raise of ~$100.0M from 2023-2024)
- Additionally, firms are shifting towards alternative financing options (e.g., licensing, royalty deals, structured debt, PIPEs, etc.)
- Of the 85 follow-ons YTD[1], only 18 (~21%) are currently trading above their issue price

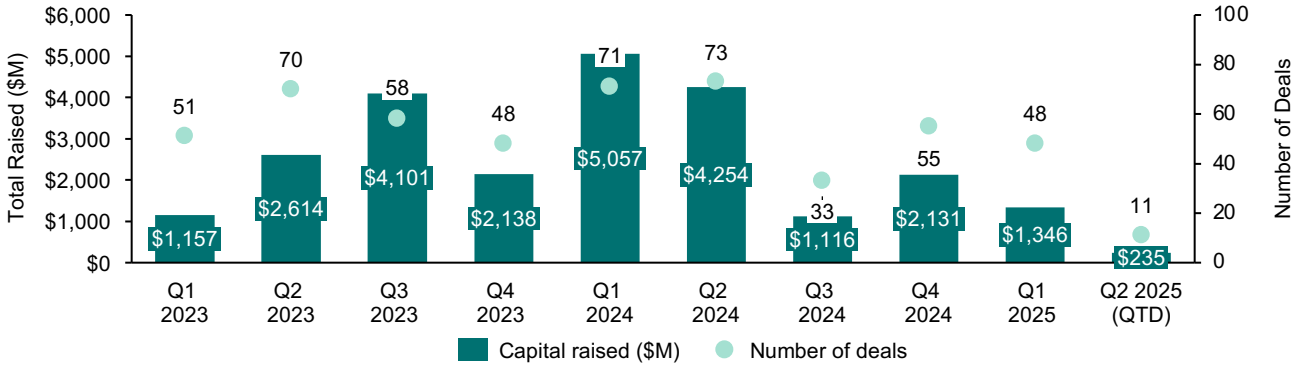
1. As of 5/9/2025

Sources: CapIQ

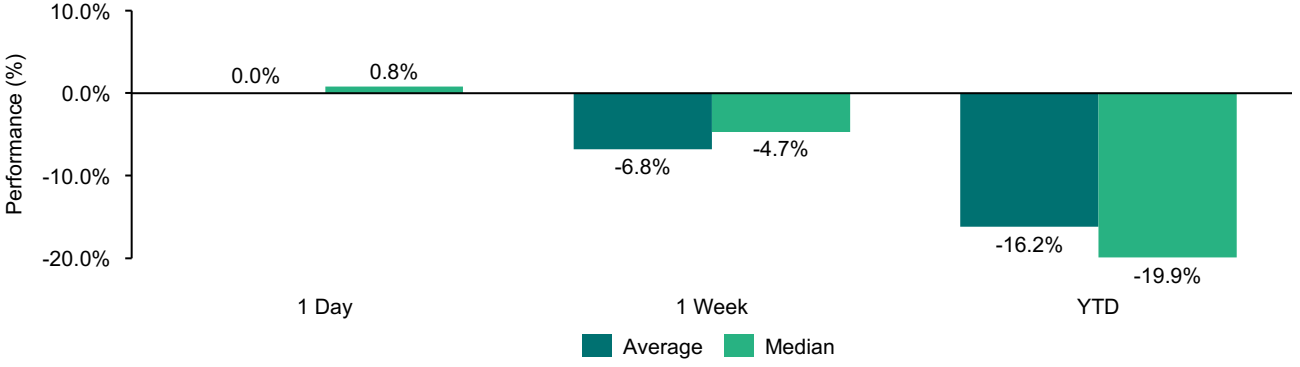
Aggregate proceeds raised for PIPEs / RDOs in Q1 2025 has meaningfully decreased from the highs of H1 2024

US & Europe Healthcare PIPEs / RDOs Breakdown

PIPEs / RDOs by Quarter (2023 - YTD)



After Market Performance of 2025 PIPEs / RDOs[2]



Key Takeaways

PIPE / RDO activity in Q1 2025 sharply decreased from the highs in Q1 2024, while after market performance has been poor

- PIPE / RDO activity is well behind the watershed quarters of Q1 and Q2 2024
- Of the 59 PIPEs / RDOs YTD, only 16 (~27%) are currently trading above their issue price
- Deal sizes are down as indicated by Q1 2025 having an average deal size of $28.1M compared to $50.1M from 2023 - 2024, which may be driven by:
  - Reduced investor appetite for small/mid-cap biotech
  - Compressed valuations
  - Modest returns on PIPEs
  - Reliance on more specialist funds (vs. generalist investors)
- Additionally, volume has decreased ~14% compared to the average over the previous two years (~56 deals per quarter)

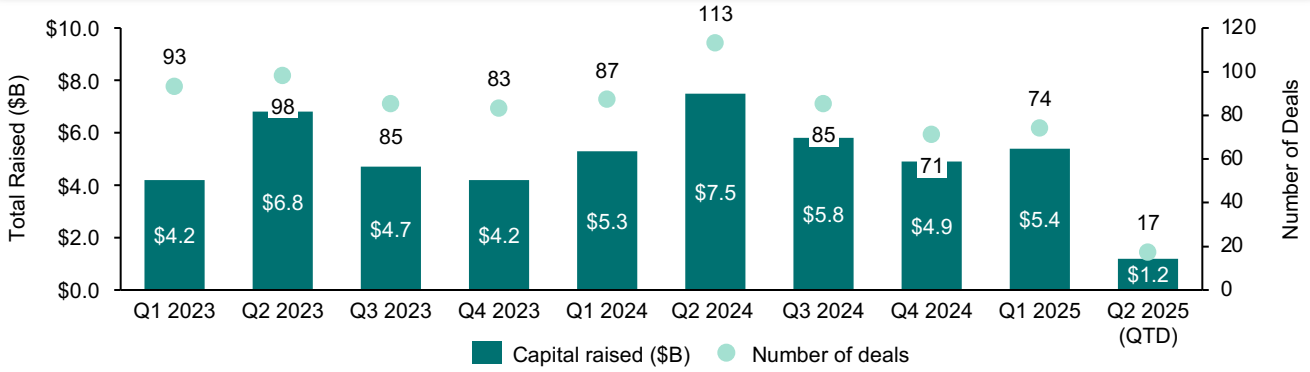
1. As of 5/9/2025
2. Only includes PIPEs/RDOs that disclose the issue price

Sources: BiomedTracker

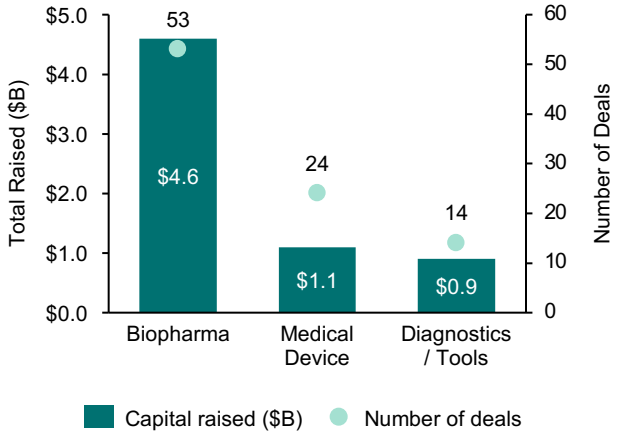
Venture capital raised in Q1 2025 has remained consistent on a YoY basis due to a handful of mega-rounds, while seed funding has dried up

US & Europe Healthcare Venture Breakdown[1]

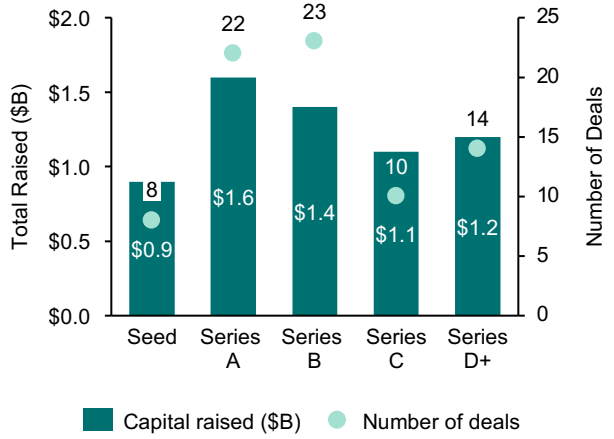
Venture Deals by Quarter (2023 - YTD)



Venture Deals by Sector 2025 YTD



Venture Deals by Round 2025 YTD



Key Takeaways

Total proceeds raised for venture in Q1 2025 was in line with Q1 2024 due to fewer but larger check sizes

- Despite the volume of deals in Q1 2025 being the second lowest quarter over the past two years, total capital raised was buoyed by higher average rounds
  - Q1 2025 had an average deal size of $73.5M compared to an average round of $59.5M from 2023 - 2024
- Seed financings had one of the worst quarters on record
- Medical devices and diagnostic / tools financing are on pace to raise more than 2024 (medical devices raised $2.2B and diagnostics/tools raised $2.4B in 2024)
- Within biopharma, oncology led by volume (12) followed by neurology (10), consistent with trends seen in previous years
- Late-stage (Phase 2/3) biopharma companies accounted for ~45% of capital raised to-date (a ~10% increase compared to all of 2024) as investors seek de-risked opportunities

1. As of 5/9/2025
Sources: BiomedTracker

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