

MedDevNews

Q4 2025

 ENGLAND & COMPANY
INVESTMENT BANKING









20 YEARS
OF TRUSTED ADVICE

Featuring:

- Quarterly Overview
- Market Trends
- Relevant Transaction Activity

Q4 2025 Market At A Glance

MedDevNews provides an exclusive quarterly summary into market trends, recent private finance and merger and acquisition activity, as well as major news stories within the Medical Device sector.

OEM M&A		50 Transactions	11.1% Change YoY		\$21.6 billion Transaction Value	NM Change YoY
CMO M&A		13 Transactions	225.0% Change YoY		N / A Transaction Value	N / A Change YoY
Private Financings		205 Transactions	-24.1% Change YoY		\$2.7 billion Transaction Value	-1.7% Change YoY
IPOs		7 IPOs	40.0% Change YoY		\$8.0 billion Transaction Value	NM Change YoY
Public Companies		4.1x Median EV / Revenue	14.5x Median EV / EBITDA		+7.2% Median Revenue Growth YoY	65.3% Median GM

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Sources: S&P Capital IQ

Q4 2025 Quarterly Overview



FDA Provides Guidance on Wearables

In Q4, the FDA’s engagement with the wearables industry reflected continued efforts to clarify how advanced biometric features will be regulated. The agency issued a warning letter to WHOOP, reinforcing that certain health-related claims may require medical device clearance. More broadly, the FDA signaled that some wearable features could qualify under general wellness exemptions if they avoid diagnosing or treating specific conditions. The agency also indicated an interest in modernizing its approach to digital health oversight to better align with evolving consumer technologies. These developments provide additional guidance for wearable developers as they expand functionality while seeking to remain outside formal device classification.



Foundation Models Gain Traction in Imaging

Foundation models, large-scale AI models with a diverse range of applications, have emerged as a major trend in imaging in Q4, with early traction concentrated in radiology. These models can be adapted across multiple imaging applications, including detection, triage, and workflow support. Several major imaging players and AI vendors have announced efforts to integrate foundation models into MRI, CT, and X-ray platforms. The FDA has started to implement regulatory frameworks for the models, with some tools already receiving clearance, such as those developed by Aidoc, HOPPR, and Radiology Partners. As imaging volumes increase, foundation models may support gains in efficiency and consistency, though questions around validation and deployment at scale remain.



Improving Orders Support CMO Outlook

Toward the end of 2025, investor interest in medical contract manufacturers strengthened as order patterns showed signs of improvement following a prolonged Covid-induced inventory correction cycle. Several larger CMOs reported stabilizing demand and inventory activity, particularly in development and higher-value services. The market has responded with renewed interest, including high-profile transactions such as the IPO of Medline, the largest healthcare IPO ever, and the announced spin-off of Teleflex Medical OEM to Kohlberg and Montagu. These transactions reflect growing confidence in the sector’s long-term growth. As 2026 approaches, we expect improving visibility into ordering behavior to support both M&A and public market activity for the CMO segment.

Sources: MedTech Dive, Newsweek, Wall Street Journal, Fierce Biotech

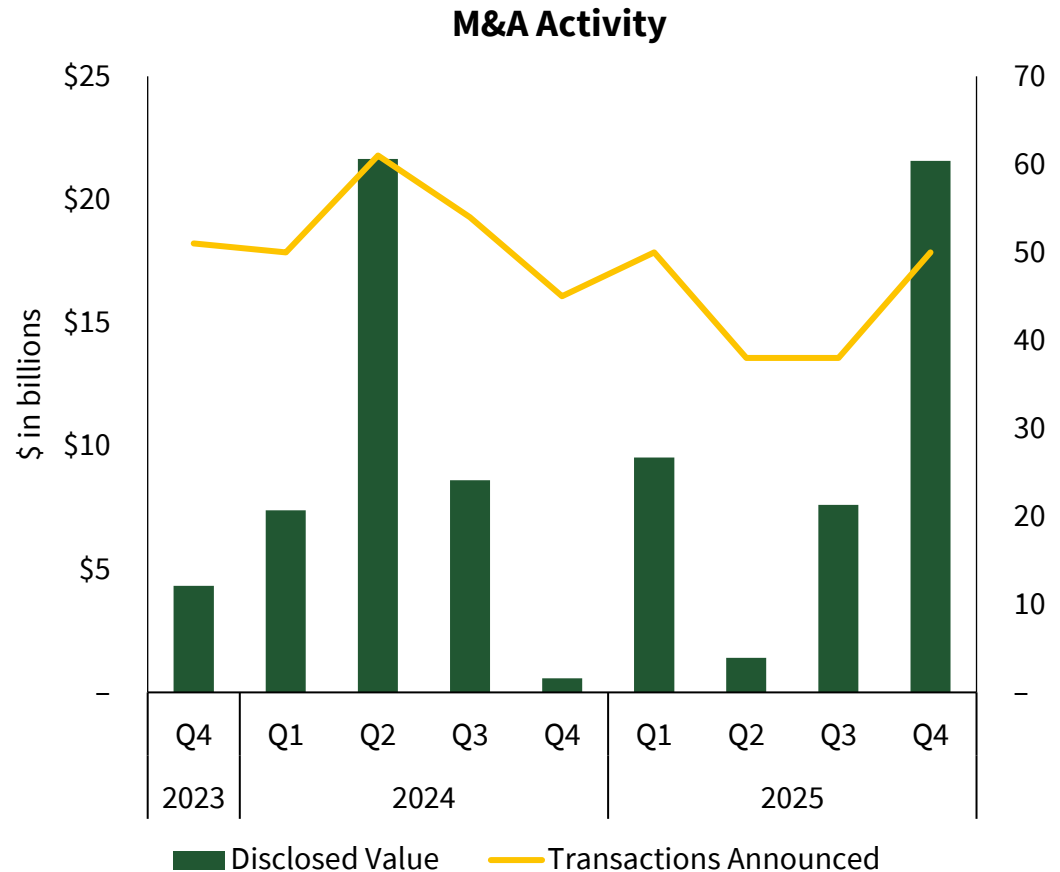
OEM Merger & Acquisition Activity

The OEM M&A market recorded 50 transactions in Q4 2025, representing a 31.6% increase from the prior quarter and returning activity to Q1 levels.

Total disclosed transaction value climbed sharply to \$21.6 billion, tying Q2 2024 for the highest quarterly total in the historical period.

OEM M&A activity moved in line with the broader market, which posted one of its strongest quarters in recent years amid improving market conditions and renewed investment which helped drive higher deal flow.

In the broader sector environment, portfolio optimization by large strategics and continued private equity appetite for scaled platform assets contributed to stronger transaction momentum. Aggregate transaction value in Q4 was largely driven by Blackstone and TPG's \$18.4 billion acquisition of Hologic.



Source: S&P Capital IQ

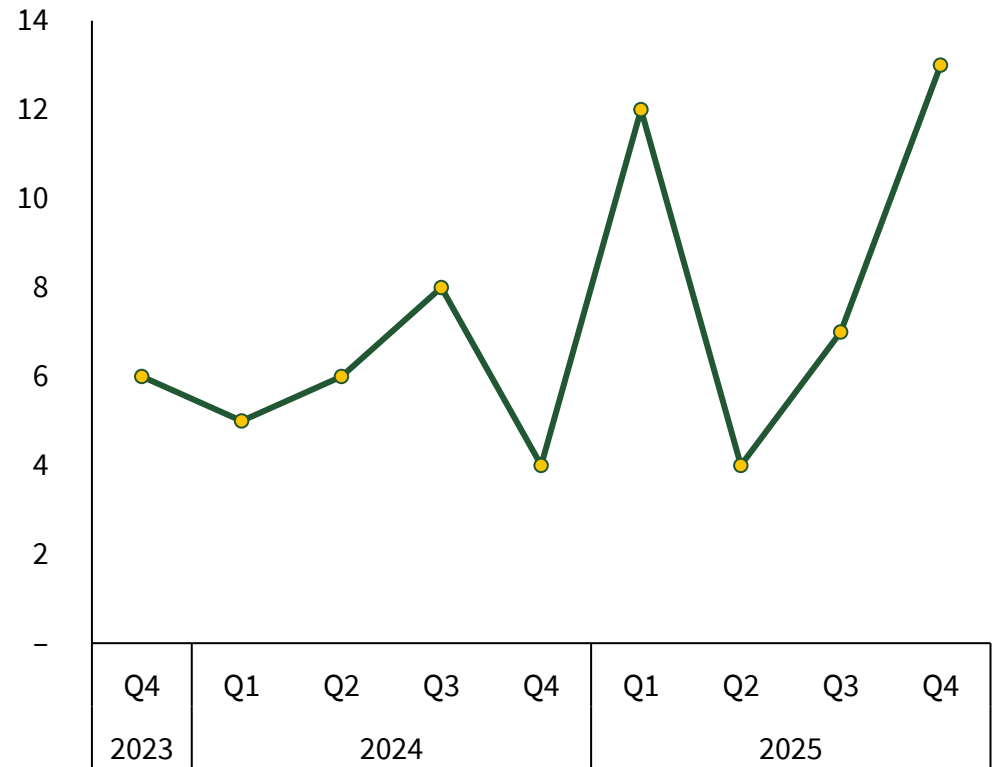
CMO Merger & Acquisition Activity

The CMO space experienced its strongest quarter of M&A in the historical period, with 13 total transactions completed. This represents a 56.5% year-over-year increase relative to 2024, driven primarily by activity in Q1 and Q4.

We believe this rebound reflects a renewed willingness to pursue transactions following a more cautious tone earlier in the year, this more active trend we expect to carry into 2026.

Activity in the CMO segment during the quarter was bolstered by a long-awaited rebound in orders across select CMO segments and a positive outlook into 2026. Additionally, larger CMOs with more complex manufacturing, strong regulatory track records, and multi-site footprints were better positioned to benefit from these tailwinds. Both financial and strategic buyers remain focused on platforms with some scale that have established customer relationships.

M&A Activity



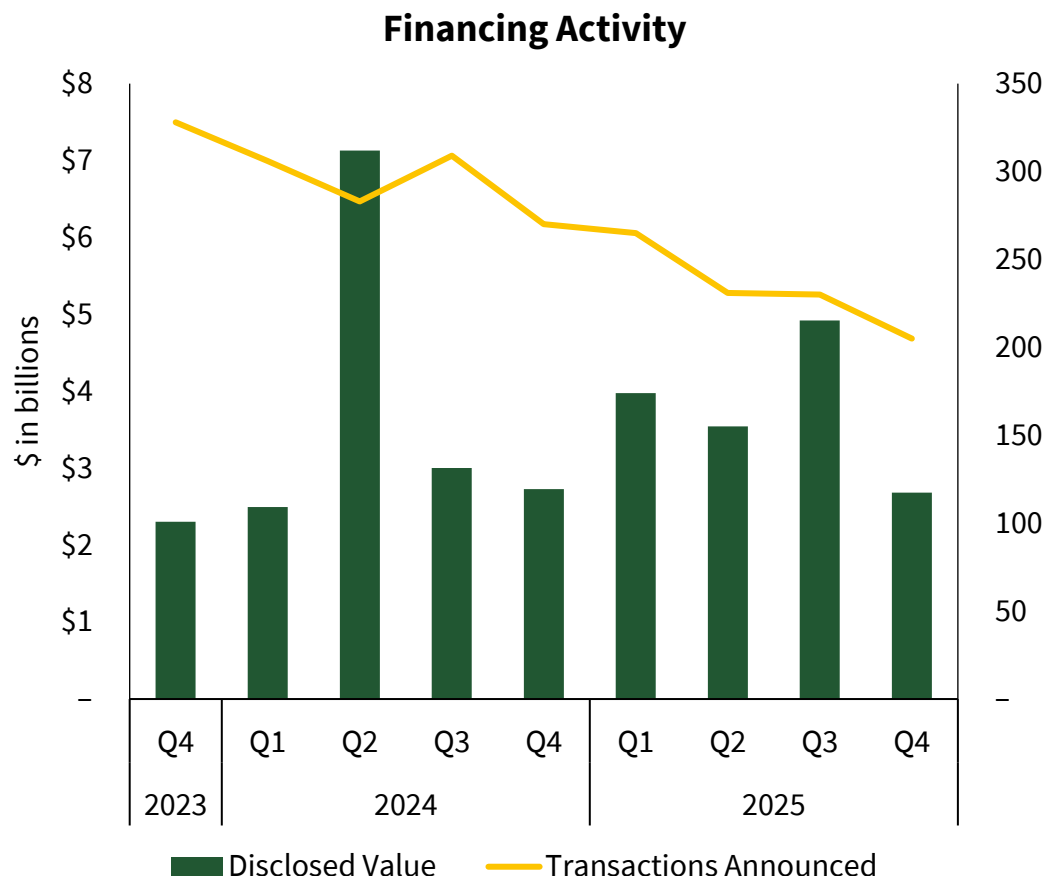
Source: S&P Capital IQ

Private Financing Activity

A total of 205 financing transactions were recorded in Q4 2025, representing a 10.9% decline from Q3 and a 24.1% decrease compared to Q4 2024. The average investment size also fell 38.8%, from \$21.4 million to \$13.1 million, further reflecting a more prudent investment environment during the quarter.

After remaining flat in the prior quarter, private financing activity continued its longer-term downward trend in Q4, reflecting ongoing liquidity constraints among smaller venture funds. The fundraising landscape remains competitive, with capital increasingly concentrated among the largest and most established investors.

Looking ahead, we expect financing activity to recover over the course of 2026 as sustained M&A activity encourages larger investors to move earlier in the risk curve, particularly toward medical technology companies that have not yet achieved regulatory clearance or significant scale.

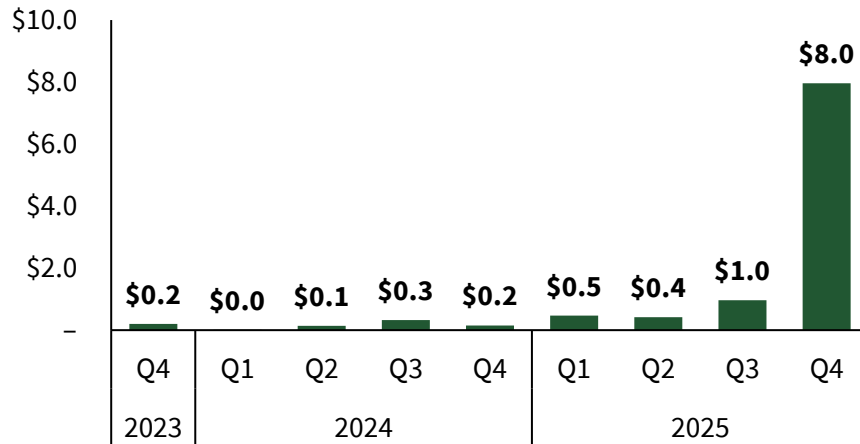


Source: S&P Capital IQ

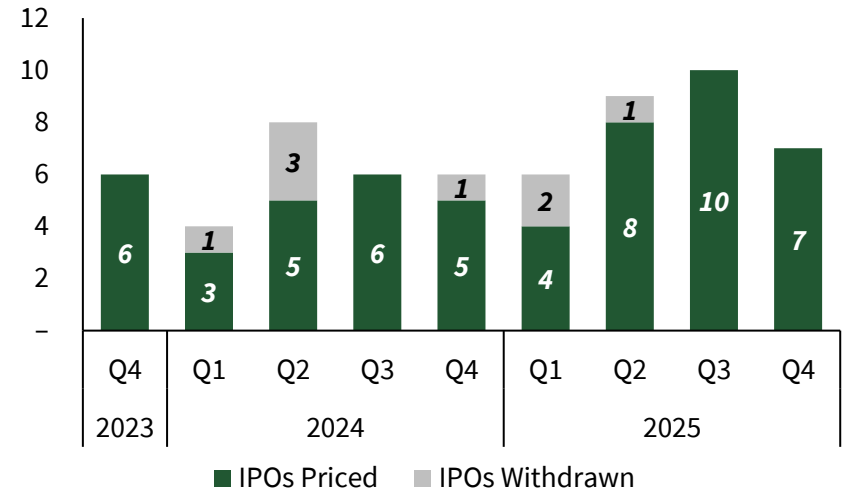
IPO Activity

(\$ in billions)

Priced IPO Value



IPOs Priced vs Withdrawn



(\$ in millions except per share data)

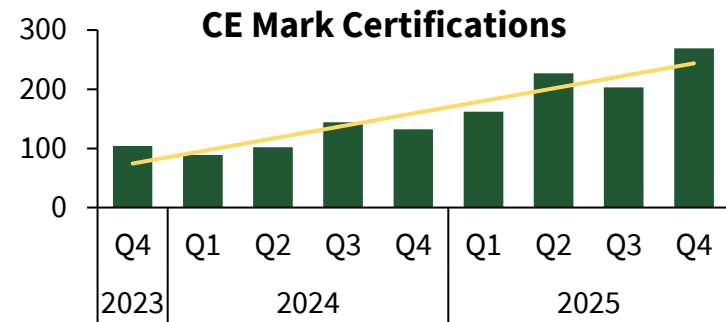
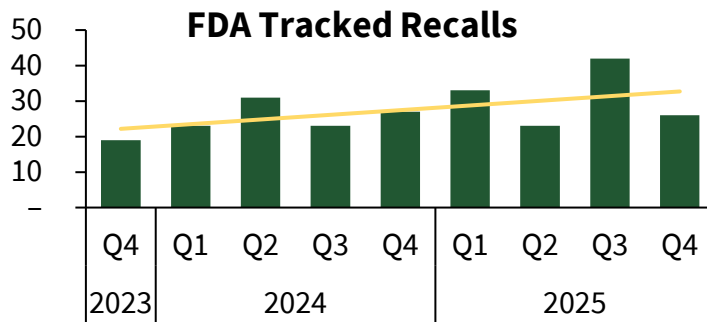
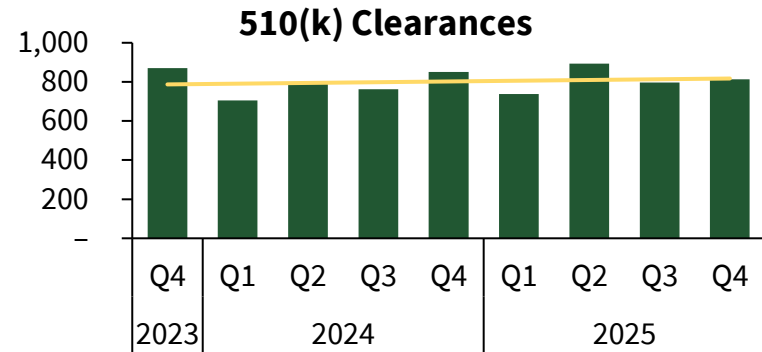
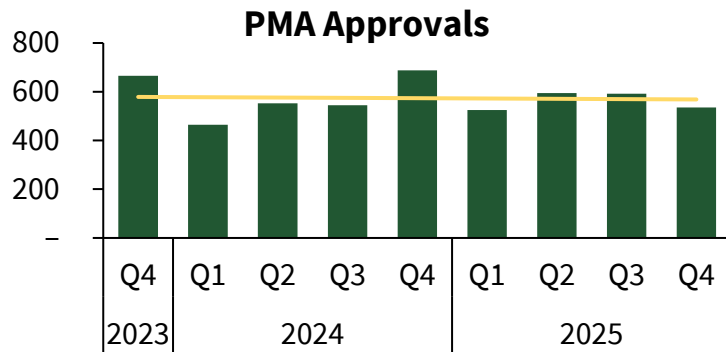
Notable Q4 2025 IPOs

Company	Pricing Date	Description	IPO Share Price	% of Midpoint	Gross Proceeds	Post-\$ Valuation	Post-\$ Valuation / NTM Revenue
MEDLINE	12/16/25	Medical manufacturing	\$29.00	103.6%	\$7,205	\$32,790	1.1x
minimed	3/5/26	Diabetes management	\$20.00	75.5%	\$560	\$5,500	1.7x
saluda MEDICAL	11/21/25	Spinal stimulation systems	\$1.87	N/A	\$152	\$212	2.5x

Source: S&P Capital IQ

















Regulatory Trends

In Q4 2025, PMA approvals experienced a modest decline from the prior quarter, falling below the median of the historical period. 510(k) clearances in the quarter totaled 813, a slight increase from last quarter and closely in line with the historical median. FDA-monitored recalls fell meaningfully from Q3 levels, declining 38% to 26. CE Mark Certifications continued to rise, reaching a historic high of 269. This reflects the impact of legislative action taken in Q3 as EU members advocated for reforms to the certification framework to overhaul the process for greater quality and efficiency control. Overall, regulatory activity in Q4 reflected mixed U.S. trends alongside improving momentum in Europe, suggesting a stabilizing approval environment heading into 2026.



















Sources: FDA.gov, EC Europa

Q4 2025 Notable OEM M&A Transactions

Target	Target Description	Acquirer	Announced Date	Target Enterprise Value (millions)	Enterprise Value/ LTM Revenue	Enterprise Value/ LTM EBITDA
 HOLOGIC® The Science of Sure	Women's health imaging and surgical systems	 Blackstone TPG	October 2025	\$18,376	4.5x	13.4x
 HOGY HOGY MEDICAL CO., LTD.	Surgical kits, disposables, minimally invasive tools	 CARLYLE	December 2025	883	3.6x	16.2x
 ACERA SURGICAL	Electrospun regenerative surgical biomaterials	 solventum	November 2025	850	N/A	N/A
 nalu™ neurostimulation	Implantable neuro-stimulation systems	 Boston Scientific	October 2025	533	N/A	N/A
 ABYRX	Surgical biomaterials and therapeutic devices	 MedEdge Holdings	November 2025	450	N/A	N/A
 ADDvise	Laboratory equipment, devices, consumables	 AMPLEX	December 2025	234	1.3x	6.4x
 oticon	Bone-anchored hearing and cochlear implants	 impilo	October 2025	93	N/A	N/A
 DJO® Dr. Comfort Footcare Solutions	Lower-extremity orthopedic products	 PROMUS	October 2025	60	N/A	N/A
				Median	3.6x	13.4x

Source: S&P Capital IQ

Q4 2025 Notable CMO M&A Transactions

Target	Target Description	Acquirer	Announced Date	Target Enterprise Value (millions)	Enterprise Value/ LTM Revenue	Enterprise Value/ LTM EBITDA
	Catheters, sutures, surgical instruments		October 2025	\$1,500	4.4x	N/A
	Catheter manufacturing equipment and tooling		October 2025	685	N/A	N/A
	Orthopedic, spinal, dental implants and instruments		December 2025	215	1.1x	7.1x
	Ophthalmic frames, lenses, and components		December 2025	162	0.6x	9.1x
	Silicone and plastic molded components		October 2025	158	3.3x	15.0x
	Pressure, force, and tactile sensing systems		December 2025	16	N/A	N/A
	Medical electronic, therapeutic systems		October 2025	N/A	N/A	N/A
	Neonatal incubators and transport systems		October 2025	N/A	N/A	N/A
				Median	2.2x	9.1x

Source: S&P Capital IQ

Q1 2026 Developing Trends



Growing Cybersecurity Demands in Medical Devices

Cybersecurity is expected to remain a focus in coming years as medical devices become increasingly integrated within hospital IT and cloud-based systems. As connectivity expands across imaging platforms and monitoring devices, exposure to cyber threats increases. Recent regulatory guidance has reinforced expectations for stronger cybersecurity risk management in both pre-market submissions and post-market oversight. As personal medical data becomes more valuable, device manufacturers will need to incorporate heightened security considerations into product design and lifecycle management. Sustained investment in cybersecurity will likely remain necessary as device ecosystems continue to expand.



MDUFA Negotiations Advance Around Device User Fees

Negotiations over the next Medical Device User Fee Amendments are underway to replace the current framework set to expire next year and are focused on user fee levels and the FDA's performance commitments for device review. Discussion points include proposed fee increases, revisions to review time for premarket submissions, and potential updates to total product lifecycle advisory meeting programs that support sponsors during development. Stakeholders are also debating how to stabilize and retain review staff following recent workforce disruptions, given the importance of predictable review resources. As talks progress, medical device companies are assessing how changes to fees and review metrics could influence regulatory timelines and pipeline planning.



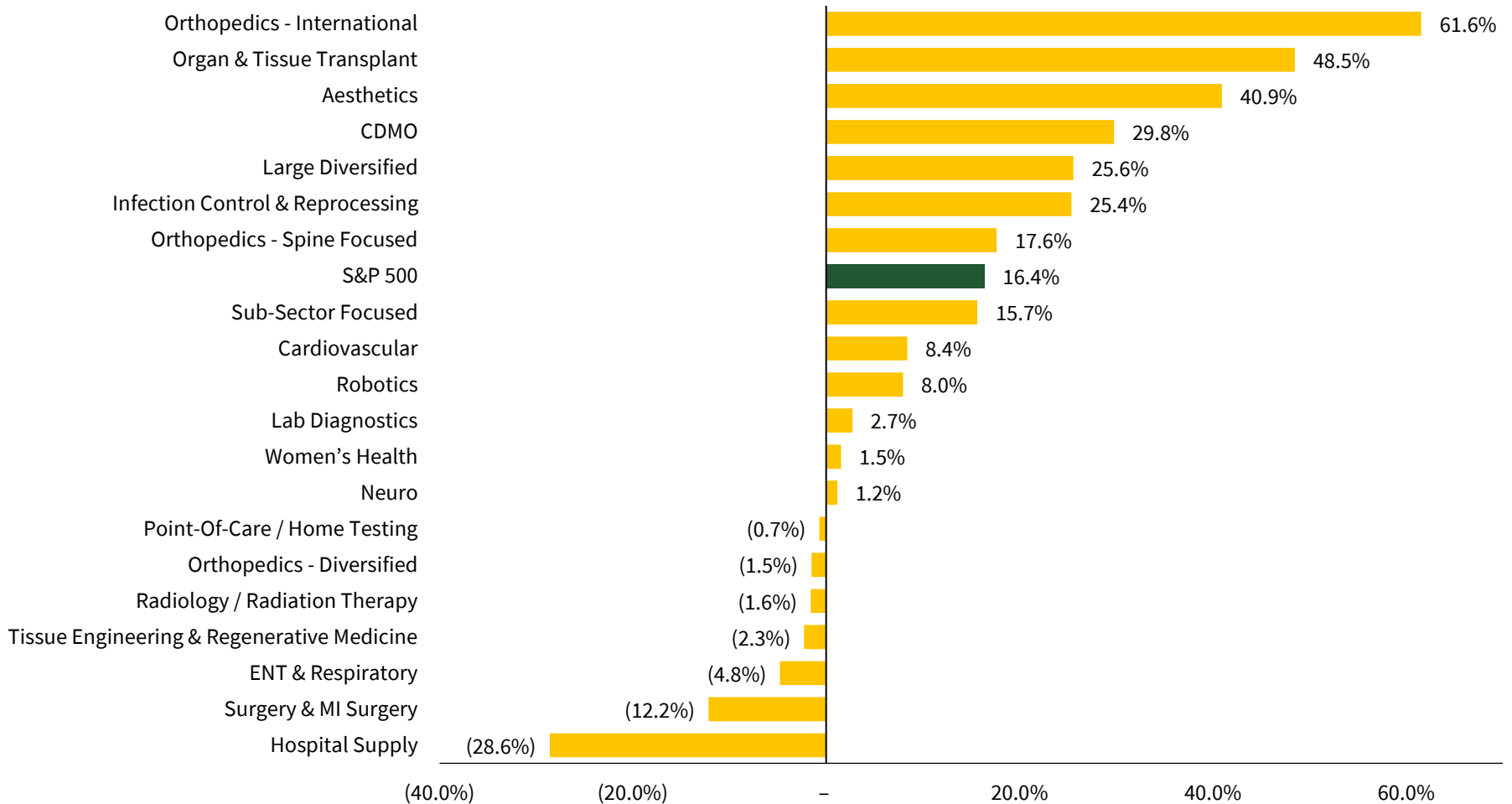
ACA Changes Create Coverage Uncertainty

Heading into 2026, changes to ACA premium subsidies and renewed debate over a federal healthcare framework are introducing uncertainty into coverage dynamics. Enhanced premium tax credits that supported marketplace enrollment expired at the end of 2025, and absent legislative action, higher premiums could lead to coverage losses among price-sensitive populations. At the same time, the administration has outlined a new healthcare proposal focused on cost transparency and expanded plan flexibility, though many details remain undefined. For medical device manufacturers, shifts in coverage levels and plan design could influence patient access, elective procedure volumes, and reimbursement trends in the near future.

Sources: Health Care Compliance Association, PTC Inc., MedTech Dive, CNBC, Infectious Disease Advisor

Public Market Performance

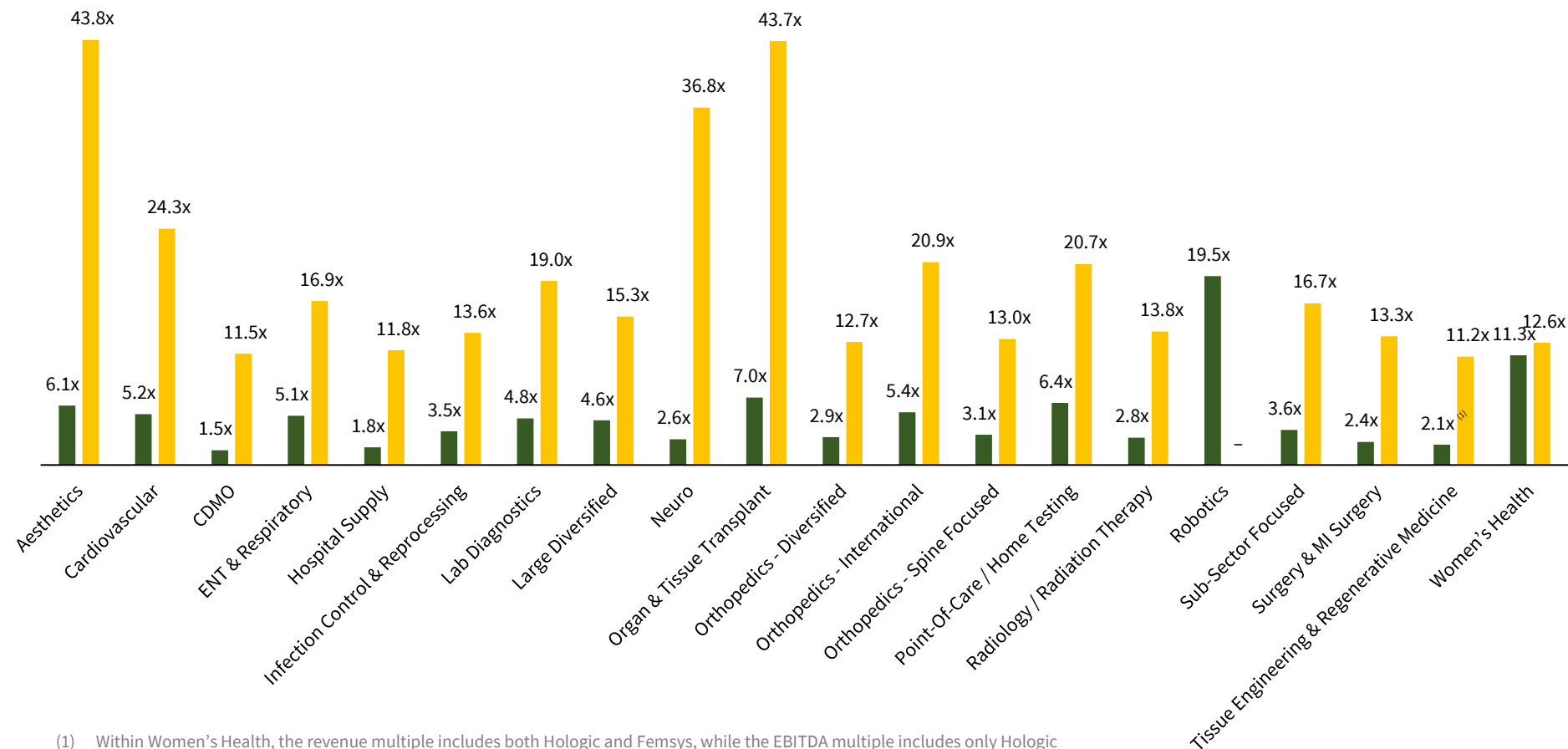
12-Month Stock Returns



Source: S&P Capital IQ (as of 12/31/2025)

Public Company Analysis by Sector

■ EV / Median LTM Revenue ■ EV / Median LTM EBITDA



(1) Within Women's Health, the revenue multiple includes both Hologic and Femsys, while the EBITDA multiple includes only Hologic

Note: Multiples are based on earnings reported through the quarter-end date of this issue

Source: S&P Capital IQ (as of 12/31/2025); Companies with multiples less than 0x or more than 50x are excluded. As a result, aesthetics, neuro, and robotics do not display EV / EBITDA multiples

Recent Medical Device Experience



ENLIGHTENING INNOVATION

has been acquired by



Sell-Side Advisor



has been acquired by



Sell-Side Advisor



\$38,500,000
Series C Preferred Stock



Exclusive Placement Agent



has entered into a strategic relationship with



Exclusive Financial Advisor



\$25,000,000
Debt Financings

Exclusive Financial Advisor



\$12,700,000
Series C-1 Preferred Stock



Exclusive Placement Agent



has been acquired by



Sell-Side Advisor



has been acquired by



PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Sell-Side Advisor



has been acquired by



Sell-Side Advisor



\$31,000,000
financing by



Financial Advisor



has been acquired by



Sell-Side Advisor



has received an investment from



Financial Advisor



has been acquired by



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