Bio CDMO (Industry and Capital Markets Report)

(By SP2 Analytics)

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Who We Are

We specialise in providing quality offshore analysts who help our clients effectively manage their work in the field of investment research and data analytics. We also create custom AI solutions for investment research workflows.

Incorporated in India, we are a trusted partner for Investment Banks, Equity Research, Private Equity Firms, and Asset Management Companies.

As an investment firm, we had the opportunity to work closely with SP2 Analytics and his team across several high-impact projects (equity research, investment banking and private equity).
SP2/ Siddhartha's consistent and dependable service made it easier for our team to focus on strategic execution while relying on him for seamless research and analytics.

- Ex-Managing Director at EQT and Director at KKR

The professional approach to building and maintaining financial models, conducting research, and assisting in writing various initiation and industry reports was commendable. Efficient handling of the work allowed me to focus on a more strategic business development role

- Ex-Equity Research Director at Stifel

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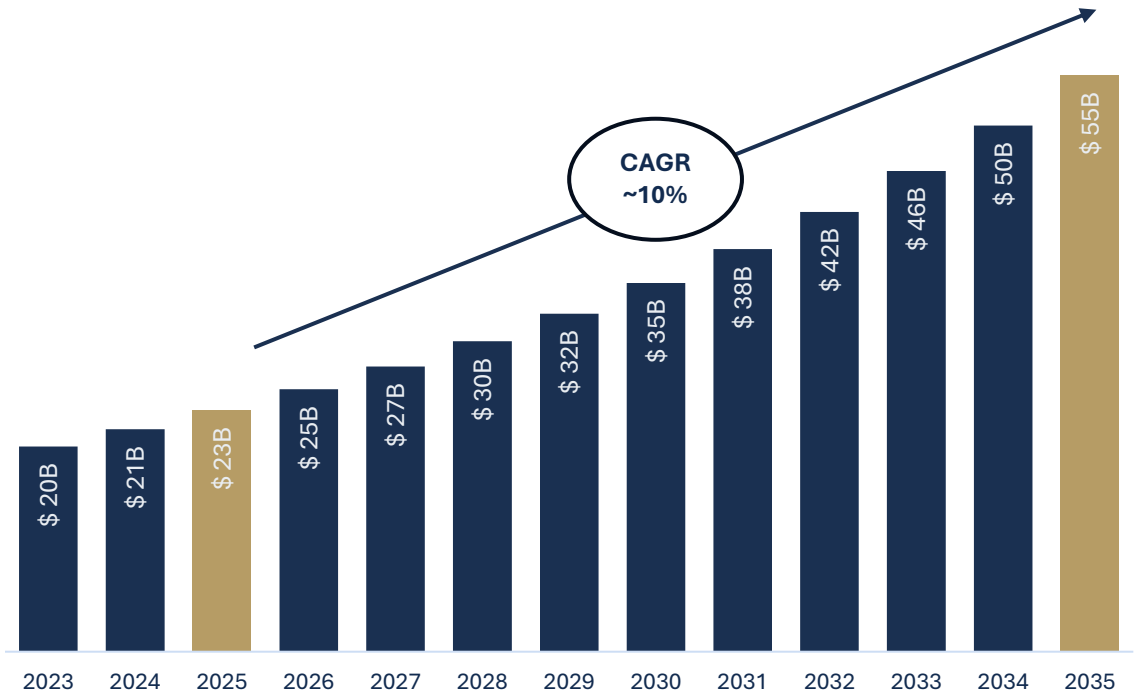
Gist of the Report

Market Size
~$23B

CAGR %
~10%



Bio CDMO market size

Executive Summary

- The Bio CDMO market is expected to grow at ~10% CAGR, expanding from around $23B in 2023 to over $50B in the long term.
- The industry is witnessing a structural shift toward outsourcing driven by increasing biologics complexity and capacity limitations within pharma companies.
- The industry benefits from high barriers to entry, including significant capital requirements, regulatory complexity, and technical expertise, resulting in a concentrated and defensible market structure.
- Long-term growth is supported by biologics innovation, patent expirations, and ageing demographics.
- Despite post-pandemic normalisation in growth, profitability remains strong with ~40% EBITDA margins, supported by sticky client relationships and long-term contracts.
- M&A activity is a key growth driver, enabling capacity expansion and service integration. Scarcity of quality assets will continue to support premium valuations (~14x–25x EV/EBITDA).
- Near-term risks include geopolitical disruptions and supply chain challenges due to the Middle East war.

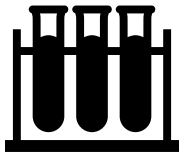
Source: Precedence Research, SP2 Analytics

Understanding the BIO CDMO Industry

Molecule to Market: How Bio CDMOs Capture Value Across the Lifecycle

Integrated services spanning development, clinical supply, commercial manufacturing, and packaging, with 80% of value concentrated in commercial stages

Bio CDMO Service

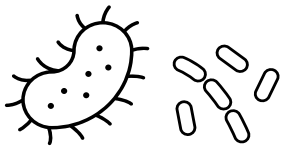


Drug Product Development

- Raw Material Sourcing
- Prototype Formulation Development
- Technology Transfer
- Process Development & Optimisation

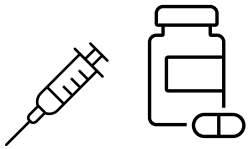
Clinical Trial Supply

- Production of investigational drug products
- Packaging & labelling for clinical studies



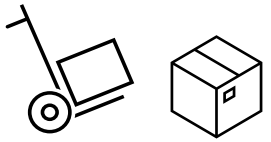
API / Drug Substance Manufacturing

- Extraction (Natural Sources)
- Chemical Synthesis
- Microbial Fermentation
- Mammalian Cell Culture
- Cell & Gene Therapy Manufacturing



Drug Product Manufacturing (FDF)

- Formulation Development
- Oral Solid Dosage Forms
- Injectable & Sterile Drug Products
- Liquid & Semi-Solid Formulations



Packaging

- Primary Packaging
- Labeling & Serialisation
- Tertiary Packaging & Distribution Preparation

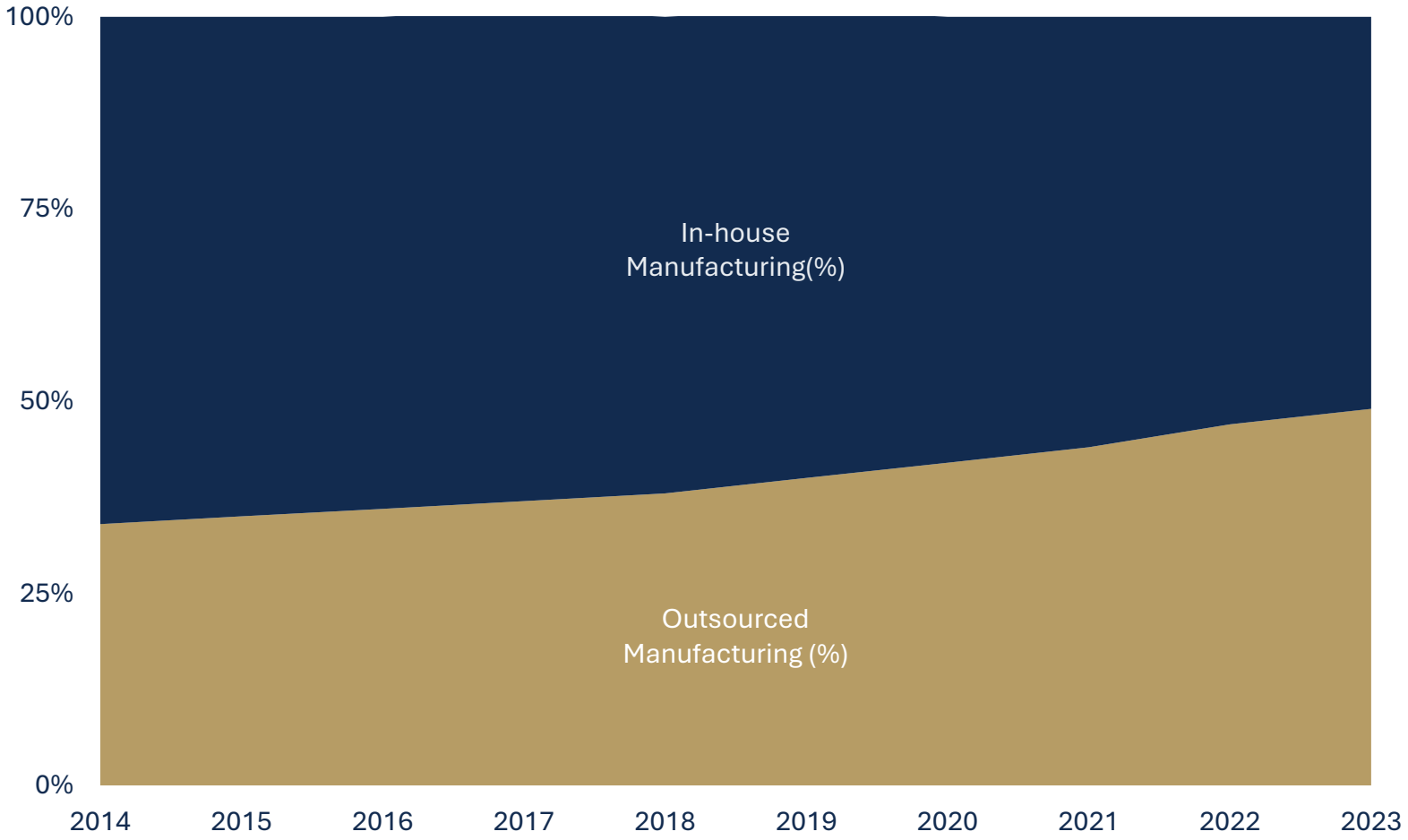
Pre Clinical Phase I → **Clinical Phase II III** → **Commercial Phase**

20% Revenue Share | **80% Revenue Share**

Source: HW Market Intelligence Report 2024, SP2 Analytics

What Drives The Shift Toward Outsourcing?

Rising biologics complexity and capacity constraints are driving pharmaceutical companies to rely more on CDMO partners



Drivers of the shift

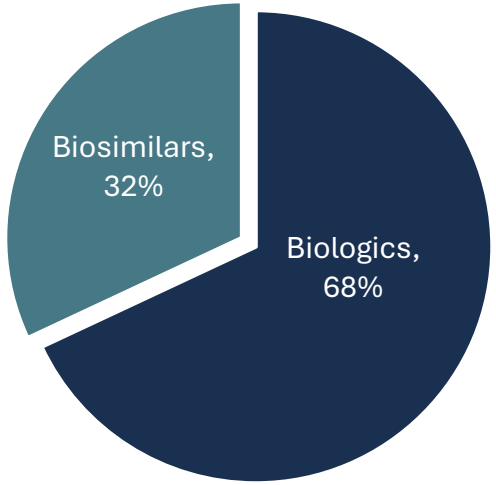
- Outsourcing in pharmaceutical manufacturing has steadily increased, rising from ~34% in 2014 to ~49% in 2023, reflecting growing reliance on external partners.
- Internal manufacturing capacity is struggling to keep pace with rising demand, particularly for complex biologics and advanced therapies.
- Outsourcing also mitigates manufacturing risks related to CMC (Chemistry, Manufacturing & Controls) while ensuring reliable and scalable production capacity.
- The trend indicates a structural shift toward greater outsourcing in the pharmaceutical value chain, and is expected to continue in the coming years.

Source: Jefferies 2025 Report, SP2 Analytics

Monoclonal Antibodies Dominate the Demand

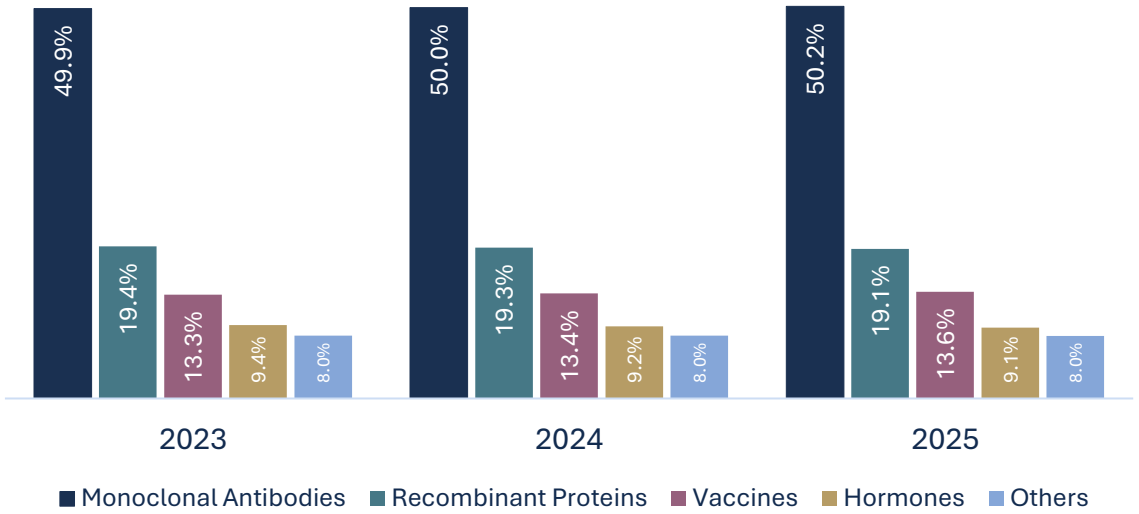
Monoclonal Antibodies continues to account for the largest share of manufacturing in 2025

Industry Mix by Product Type (2025)



- The market composition remains skewed toward biologics (~68% market share) compared to biosimilars (~32%), reflecting stronger outsourcing demand for innovative biologic drugs.
- Biosimilars indicate growing opportunities as patent expirations of major biologics increase biosimilar development and manufacturing demand.

Industry Mix by Molecule Type



- Monoclonal antibodies dominate the bio CDMO market (~50.2% share in 2025), making them the largest outsourced molecule segment as the pharma industry remains focused on oncology-related drug manufacture.
- Recombinant proteins remain the second-largest category, showing steady growth as demand increases for complex biologic therapies.

Source: Precedence Research, SP2 Analytics

Why Companies Prefer Bio CDMOs Over In-House Manufacturing?

Flexibility, capital avoidance, technical specialisation, and regulatory certainty drive outsourcing decisions vs in-house process

Avoidance of Large Capital Investments

- Manufacturing facilities require huge capex (sometimes >$1B) and ~3-4 years to build and validate.
- Outsourcing avoids fixed infrastructure costs and the risk of underutilised capacity if drug candidates fail

Specialised Technical Expertise

- Manufacturing is complex, where "process is the product."
- CDMOs provide expertise in Cell line development, bioprocess optimisation, complex modalities such as Antibody-Drug Conjugates (ADCs), cell & gene therapies

Regulatory and Quality Compliance

- Established GMP capabilities and proven regulatory records ensure compliance with global regulatory standards.
- Strong expertise in Chemistry, Manufacturing, and Controls (CMC) helps minimize regulatory risks and potential approval delays.

Manufacturing Flexibility and Scalability

- Enables companies to scale production from clinical to commercial volumes without investing in internal capacity.
- CDMOs provide flexible manufacturing capacity and integrated services, allowing rapid scale-up as drug demand grows.

Securing Capacity in Tight Markets

- Rapid growth in biologics and therapies such as GLP-1 obesity drugs is tightening global manufacturing capacity.
- Partnering with CDMOs allows companies to secure manufacturing capacity and avoid production bottlenecks.

Supply Chain and Geopolitical Risk

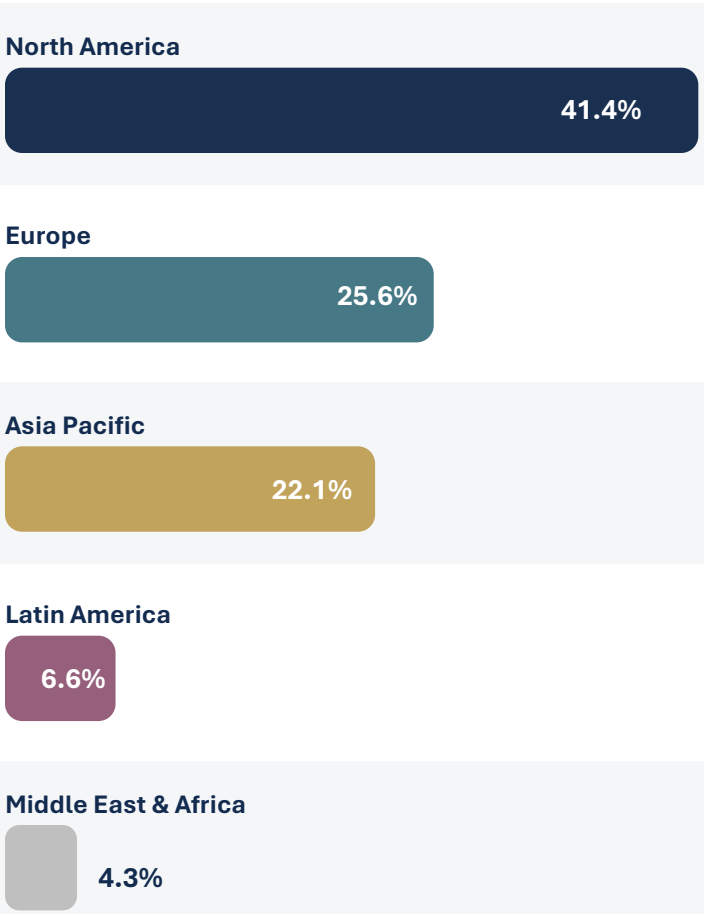
- Companies are diversifying supply chains amid geopolitical risks and uncertainty.
- Prioritising CDMOs with allied-nation manufacturing footprints to ensure supply chain security and regulatory alignment diversifies the geographic risk.

Source: SP2 Analytics

Geographical Dynamics of the Industry

Understanding Regional Dynamics of the Industry

Established Western hubs provide stability as Asia-Pacific drives incremental growth



North America	Leads the global bio CDMO market share, supported by a strong presence of major pharmaceutical companies such as Pfizer, Amgen, and Johnson & Johnson. A robust FDA regulatory framework encourages biologics innovation and investment in manufacturing capacity.
Europe	Mature market with strong regulatory standards under the EMA. Home to leading CDMOs, including Lonza and Boehringer Ingelheim, with growing demand for biosimilar manufacturing.
Asia Pacific	Fastest-growing region, driven by lower manufacturing costs, skilled workforce, and increasing foreign investment in biopharma infrastructure. Players such as Enzene Biosciences and Prestige Biologics are expanding capabilities.
Latin America	Emerging market with growing domestic demand for biologics and expanding regulatory harmonisation across key economies, including Brazil and Mexico.
Middle East & Africa	Nascent market with increasing government investment in healthcare infrastructure and pharmaceutical self-sufficiency initiatives.

Source: Precedence Research, SP2 Analytics

Structural Drivers of the Industry

What Megatrends will Power the Bio CDMO Growth Engine?

Despite current uncertainty, biotech innovation, new approvals, patent cliffs, and demographic ageing converge to power long-term demand

Increasing Complexity of New Modalities

Increasing manufacturing complexity from next-gen therapies and radiopharmaceuticals is expected to drive the need for specialised infrastructure and capabilities.

Steady increase in outsourcing mix by Pharma Companies

The share of outsourced pharmaceutical manufacturing increased from ~34% in 2014 to ~49% in 2023, reflecting a structural shift toward external CDMO partners. This shift is expected to continue for the coming years.

Biosimilar Opportunity from Major Patent Expirations

Major biologics losing patent protection before 2030: Keytruda ~$21.51, Darzalex ~$10.5B, Opdivo ~$5.8B, creating acceleration in biosimilar development, driving higher demand for bio CDMO

Rising Biologics Drug Approvals

Biologics approvals remain strong, with ~15–17 biologic drugs approved annually by the FDA. They account for ~30% of total new drug approvals.

Global Demographic Aging

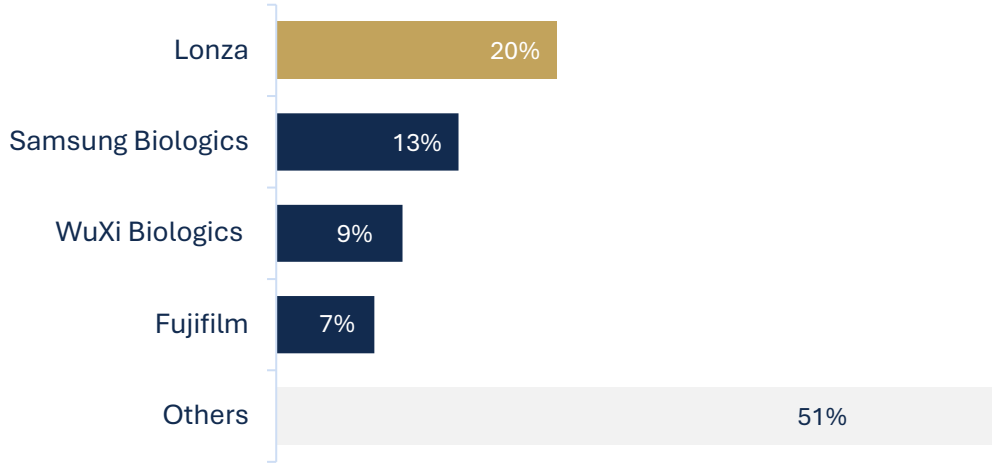
The global population aged 65+ is expected to double to ~1.5 billion by 2050, increasing the prevalence of chronic diseases such as cancer, diabetes, and autoimmune disorders, driving higher demand for biologics.

Understanding Industry Development Through the Lens of Key Players

Key Players and Their Approach to Growth and Profitability

A few manufacturers account for ~50% of industry revenue, each following a different approach to business expansion and profitability

Global Market Share of Bio CDMO Players by Revenue



- The bio CDMO market shows high concentration, with a few large players controlling ~50% of industry.
- Companies such as Samsung Biologics, Lonza, and WuXi Biologics dominate due to large-scale biologics manufacturing infrastructure.
- High capital requirements, regulatory expertise, and technological complexity create strong barriers to entry, reinforcing industry concentration.

Different Approach to Growth and Profitability	
Lonza (Stable Incumbent)	Exercised strict discipline by decreasing the capex profile since pandemic and is perfectly positioned for cash harvesting
Samsung Biologics (Steady Expander)	Maintained a strategy of continued, measured expansion with the consistent addition of new plants, securing the high margin profitability
Wuxi Biologics (Aggressive Acquirer)	Went on an expansion and acquisition spree to quickly capture pandemic momentum. FCF is vulnerable to operating leverage impacts.
Fujifilm (Outlier)	Operates with a distinctly lower EBITDA margin profile due to program failures, site losses, and expansion costs. Aims to catch up to the industry margin profile by FY-30.

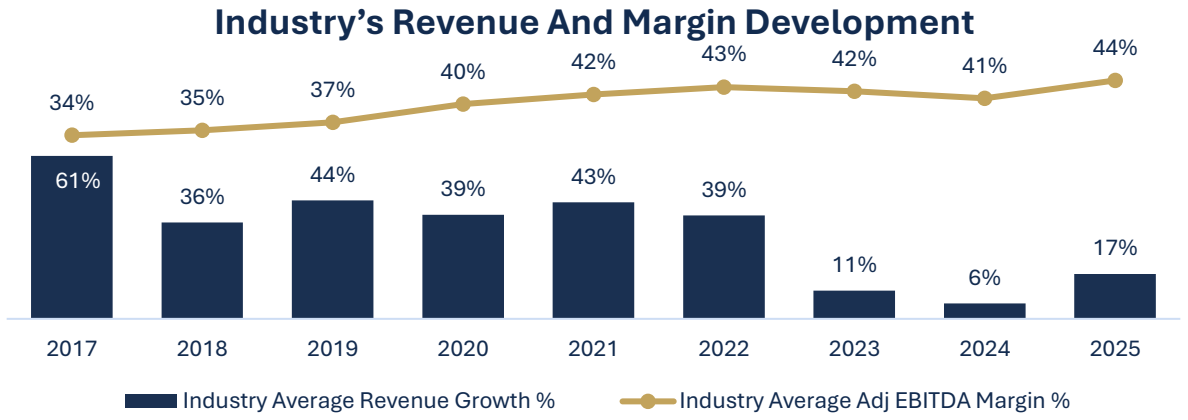
Source: Company documents, SP2 Analytics

Bio CDMO Industry is Currently in the Transition Phase

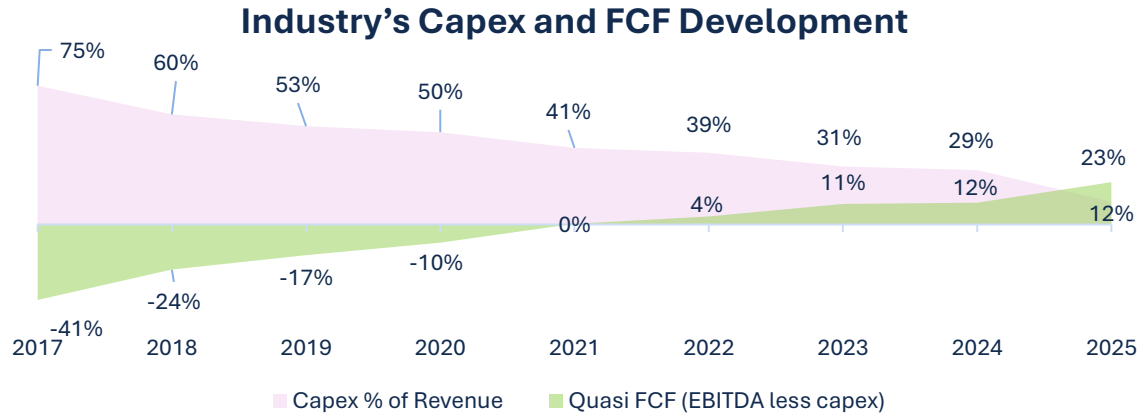
Industry Has Exited the Aggressive Expansion Phase, Transitioning Into a Mature Era of Normalised Growth, But Remains Marked by a Highly Defensible Margin Profile

Post-Pandemic Normalisation in Revenue: Following explosive, momentum-driven growth, industry revenues are stabilising into a mature, sustainable trajectory.

Margins Remain Highly Defensible: Despite the sharp tapering in revenue growth, the core business model has proven resilient, maintaining a healthy~40% adjusted EBITDA margin**(excluding margin-outlier Fujifilm).**



Reduction in Aggressive Capex is Translating to Positive FCF Margins: The aggressive capex expansion plans of the past decade have been normalising and the industry now enjoys a positive FCF margin



Source: Company documents, SP2 Analytics

Key Players Finished the Year on Continued Positive Expectations

Recent commentaries (past 2 quarters) suggest that the industry shows strong long-term growth driven by outsourcing and integrated demand, with increasingly selective Big Pharma contracting focused on quality and reliability.

Confirms a robust CDMO growth trajectory

Sees strong contracting demand for strategic projects

Observes a clear trend where pharma companies increasingly request integrated business solutions covering multiple modalities

-Lonza

Forecasts the biopharmaceutical market will grow at a 9% CAGR through 2032, while the CDMO market will expand faster at 13% due to increased outsourcing

Predicts demand for large-scale production will continue to exceed capacity

-Fujifilm

Reports robust client demand and consistent operational performance leading into 2026

Notes that Big Pharma clients are conservative and will not sign contracts without absolute trust in supplier quality and speed

-Samsung Biologics

Analysing Impact of Middle East War on the Bio CDMO Industry

Impact Assessment of Iran War on Bio CDMO Industry

Middle East Conflict Impact Assessment (Feb 28, 2026 onwards)

~50% Crude Surge

55–70% Freight Rate ↑

20%+ Oil via Hormuz

Energy & Raw Material Costs

- Brent crude surged ~50% to >$100/bbl
- Petrochemical feedstocks (PE, PP, EVA) up sharply and should have some impact on the margins (impact on COGS will depend on the activity the CDMO undertakes)

Logistics & Cold Chain

- Dubai, Abu Dhabi, Doha cargo hubs closed
- Freight rates up 55–70%
- Biologics cold-chain being rerouted

Clinical Trial Supply Risk

- Investigational drug shipments most vulnerable (since time sensitive)
- Protocol deviations and patient dropout risk are rising
- CDMOs serving biotech sponsors are most exposed

Strait of Hormuz Disruption

- Critical chokepoint for 20%+ of global oil transit
- Insurance premiums at record highs
- Shipping costs continues to increase

Biotech Funding Squeeze

- Market volatility will further dampen VC appetite
- Small/mid biotech may delay CDMO campaigns

Generic Medicine Supply

- API supply chains disrupted via Middle East routes
- Risk of drug shortages in emerging markets

Source: SP2 Analytics research, industry news

What are Strategic Implications of Iran War on the Bio CDMO Landscape?

Winners and losers will be decided by who stands to navigate disruption better

Positioned to Gain

- **US-based CDMOs**: They benefit from domestic energy feedstock access (shale gas-derived ethane), direct proximity to end-clients, and insulation from Strait of Hormuz shipping disruptions.
- **European CDMOs with integrated supply chains**: Companies with manufacturing bases in Switzerland, Germany, or Ireland are relatively shielded from Middle East logistics disruption.
- **South Korean CDMOs**: Their large-scale biologics manufacturing capacity, geographic distance from the conflict zone, and established relationships with Western biopharma sponsors make them attractive alternatives as clients accelerate supply chain diversification away from conflict-exposed routes.
- **Indian CDMOs**: The war is accelerating the already-existing China+1 diversification trend and BIOSECURE Act tailwinds (but risk of high crude price remains for some CDMO activities)

Under Pressure

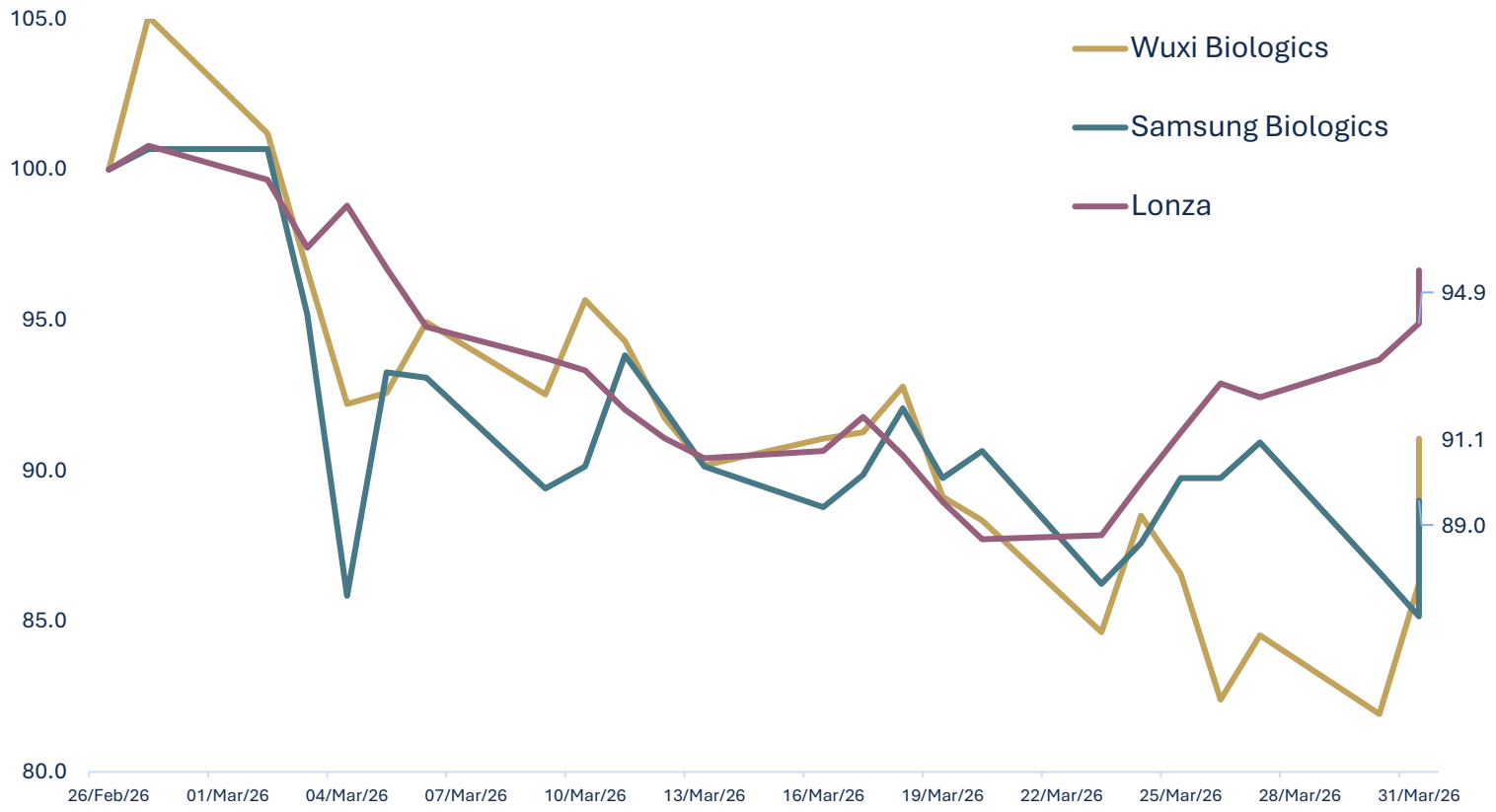
- **Thin-margin generic API and formulation CDMOs**: These operators, particularly in India, run on single-digit margins and simply cannot absorb the 55–70% freight rate spike and surging energy input costs.
- **CDMOs reliant on Gulf logistics corridors:** Companies that depend on Dubai, Abu Dhabi, and Doha as cargo hubs for shipping temperature-sensitive biologics between Europe and Asia are facing severe operational disruption, with shipments rerouted through longer, more expensive, and less reliable alternative corridors.
- **Chinese CDMOs:** Already under pressure from the BIOSECURE Act, the war is compounding their challenges.
- **Small CDMOs serving early-stage biotechs:** Small and mid-sized biotech clients, which form the core revenue base for many smaller CDMOs, are likely to delay manufacturing campaigns.

Source: SP2 Analytics

Impact of the Iran, Israel and US War on the Industry Leaders

Historically, the sector remained unfazed by the war-like scenarios, but this highly defensible business is also affected by the ongoing war

Impact of US, Israel and Iran War on Key Players Share Price



Public Markets Impact

- **Decline in stocks should NOT be driven primarily by oil prices** as oil-linked costs are not a substantial in all processes, and even large oil spikes have historically had minimal impact on margins or valuations.
- Current drop seems to be **more due to logistics disruption and overall negative volatility**, not cost inflation, as the conflict has disrupted major air cargo hubs and routes (e.g., Gulf region), affecting global cold-chain transport.
- Current scenario could lead to impacts on temperature-sensitive shipments, batch losses, and clinical trial disruptions, leading to contract risks.

Key takeaway: Focus on **logistics resilience (geography)**, not oil sensitivity; CDMOs with routes avoiding conflict zones (e.g., Korea, Europe, US) are better positioned.

Source: Capital IQ

M&A Activities in the Industry

What Purpose Does M&A Serve in the Bio CDMO Industry?

Transactions accelerate capacity expansion, service integration, market entry, and competitive positioning

Capacity Expansion	• Acquisitions added large-scale manufacturing capacity. • Enabled companies to support late-stage and commercial biologics production.
Geographic Expansion	• Deals provided manufacturing presence in key markets such as the U.S. and Europe. • Improved supply chain resilience and proximity to major biopharma clients.
Technology & Platform Capabilities	• Acquired companies brought specialised technologies (cell therapy, ADCs, microbial testing, etc.). • Strengthened advanced biologics development and manufacturing platforms.
End-to-End Biologics Services	• Integration enabled services across development, clinical trials, and commercial manufacturing. • Allowed CDMOs to offer full lifecycle support to biotech and pharma companies..
Competitive Positioning	• Acquisitions expanded the client base and biologics development pipelines. • Increased long-term manufacturing contracts as drugs move from clinical to commercial stage.

Some Landmark Deals That Redefined the CDMO Landscape

Vertical integration, geographic expansion, and speed-to-market drive high-value transactions

Lonza

- In 2024, Lonza Group acquired the Vacaville biologics facility from Roche / Genentech for $1.2B, adding ~330,000L capacity.
- Lonza Group agreed to acquire Redberry, reducing testing time from 14 - ~4 days.

NOVO Holdings

- Novo Holdings acquired Catalent for $16.5B (all-cash), taking it private; three manufacturing sites were transferred to Novo Nordisk.
- To expand manufacturing capacity and clinical supply capabilities for scaling biopharmaceutical production.

Thermo Fisher Scientific

- Thermo Fisher Scientific acquired PPD, Inc. for ~$21B in 2021, integrating it into the Laboratory Products & Services segment.
- Adding leading clinical research capabilities and expanding end-to-end services.

ICON plc

- ICON plc acquired PRA Health in 2021 through a cash-and-stock deal ($11.7B, cash + ICON shares).
- To build a leading clinical research and healthcare intelligence platform, leveraging data, technology, and global patient access.

Thermo Fisher Scientific

- Thermo Fisher acquired Life Technologies for ~$15B in 2013 and later acquired Patheon for ~$7.2B in 2017.
- Adding drug development and manufacturing services, enabling end-to-end solutions for pharmaceutical and biotech clients.

Samsung Biologics

- Samsung Biologics acquired Human Genome Sciences from GSK for $280M, gaining a 60,000L biologics manufacturing facility in Maryland (U.S.).
- Established its first U.S. manufacturing presence, strengthening the global biologics supply chain

Source: Alphasense, Company Press release

M&As Act as Scale and Capability Accelerator

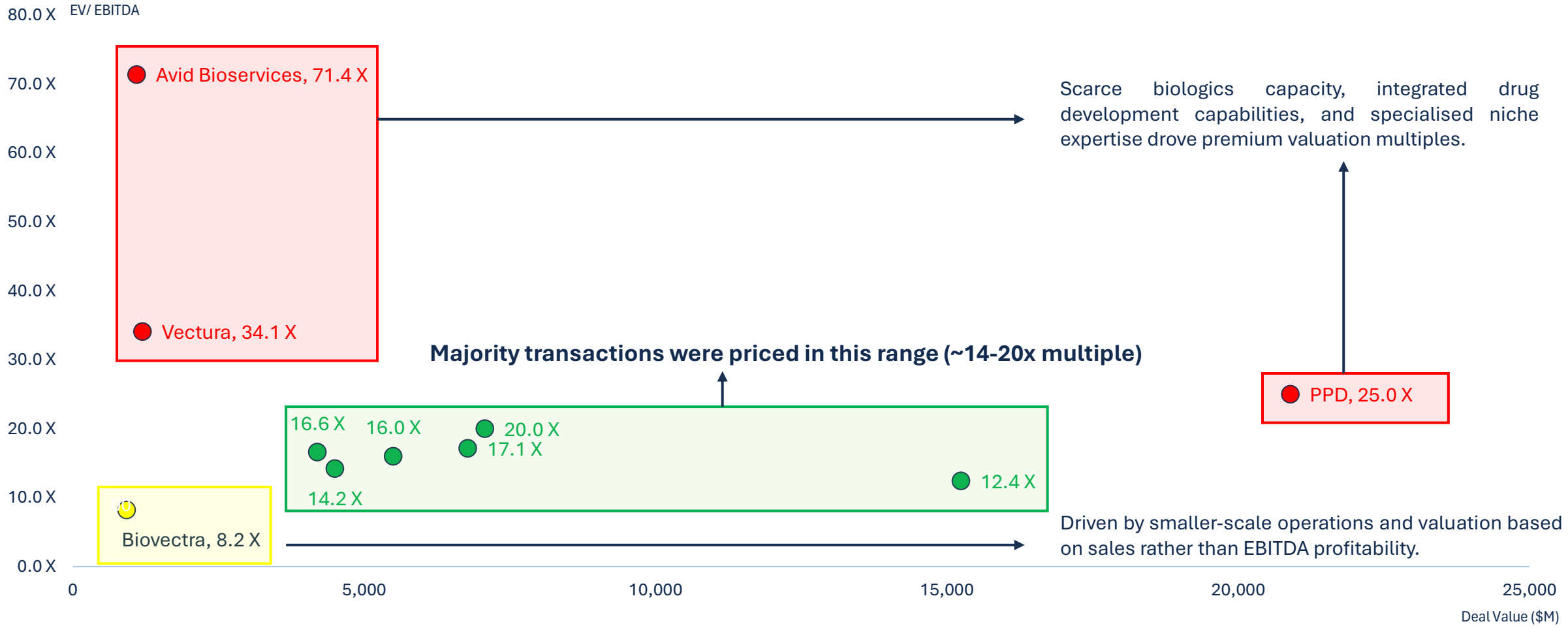
Strategic acquisitions reinforce capacity expansion, end-to-end service offerings, and market leadership

Date	Target	Acquirer	Deal Value ($M)	EV/EBITDA	EV/Sales
Dec-25	GSK Rockville Biologics Site	Samsung Biologics	280	–	–
Nov-24	Avid Bioservices	GHO Capital	1,100	71.4x	6.3x
Oct-24	Roche Vacaville Biologics Site	Lonza	1,200	–	–
Jul-24	Biovectra	Agilent Technologies	925	8.2x	–
Feb-24	Catalent	Novo Holdings	16,500	–	–
Nov-23	Forge Biologics	Ajinomoto	620	–	10.0x
May-23	ADL BioPharma	Wacker Chemical	108	16.9x	1.9x
May-22	CordenPharma	Astorg	2,600	–	–
Sept-21	Vectura	Philip Morris International	1,200	34.1x	8.6x
Jul-21	Lonza's Specialty Ingredients	Bain Capital / Cinven	4,500	14.2x	2.7x
Mar-21	PPD	Thermo Fisher Scientific	20,900	25.0x	4.4x
Feb-21	Cognate BioServices	Charles River Labs	875	–	7.8x
Feb-21	PRA Health Sciences	ICON plc	11,676	–	3.7x
May-17	Patheon	Thermo Fisher Scientific	7,076	20.0x	3.7x
May-17	inVentiv Health	INC Research	4,199	16.6x	1.8x
Dec-16	Capsugel	Lonza	5,500	16.0x	5.5x
Aug-16	BioClinica	Cinven	1,300	–	–
Apr-15	Life Technologies	Thermo Fisher	15,247	12.4x	4.0x

Source: Alphasense, SP2 Analytics

Scarce CDMO Assets Command Premium Valuations

High EV/EBITDA transaction multiples reflect scarcity of scale and qualified assets, long-term contracts, and high customer lock-ins

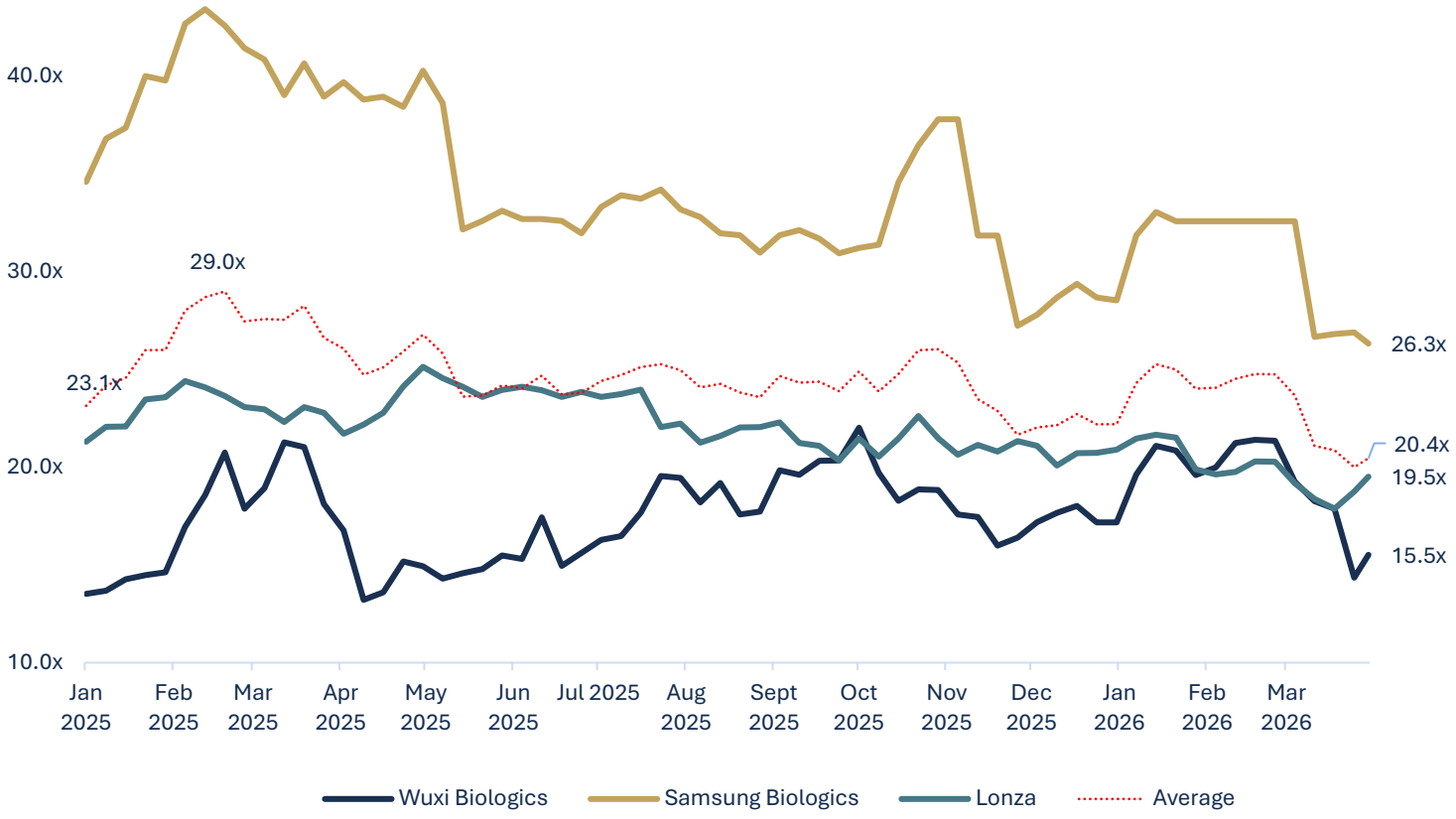


Source: SP2 Analytics

What Does Public Markets Valuation Suggest for Deals Ahead?

Current public markets multiple is at 22.0x, dropping significantly from the previous high of 29.0x seen in Feb-25

EV/ EBITDA (LTM) Multiples of Key Players



What does the valuation suggest for M&As

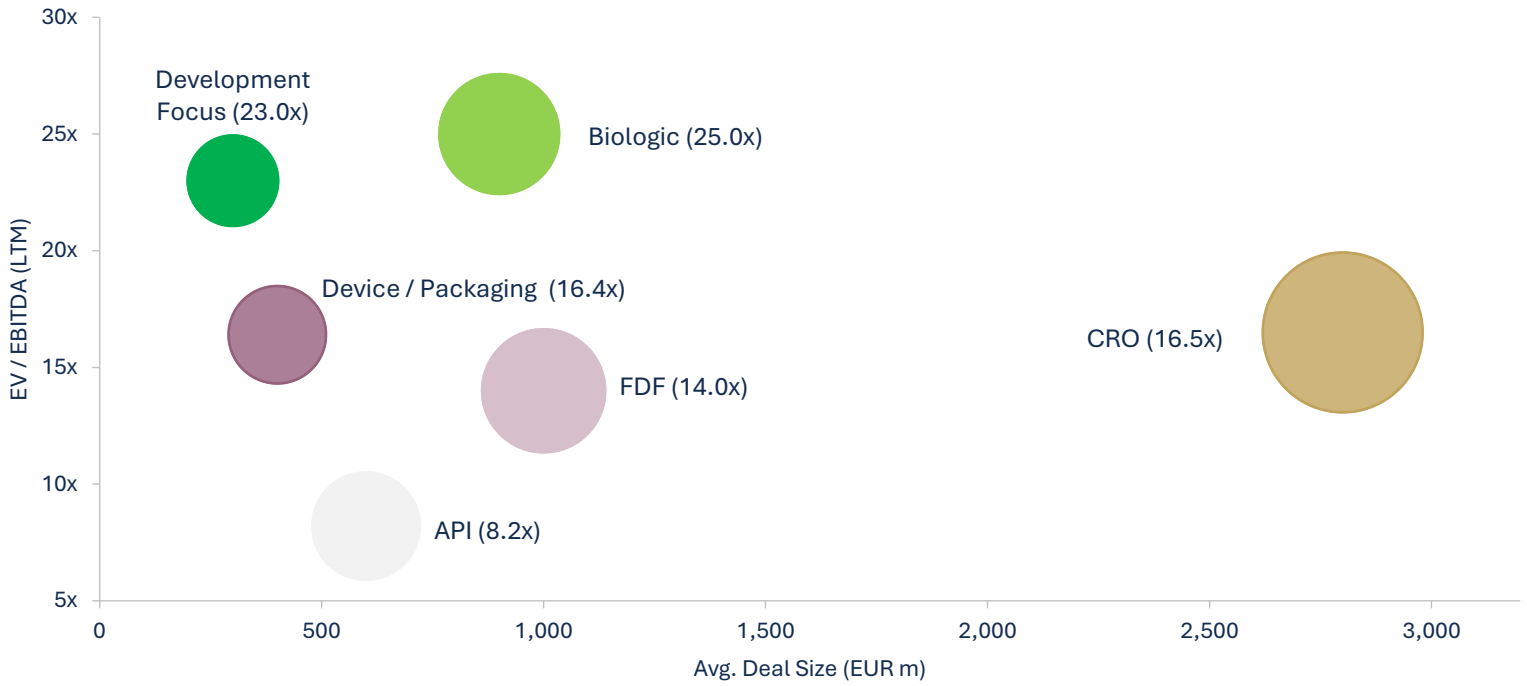
- Current public markets multiple is at ~20x, showing their premium valuations over the standard transaction multiple of ~14x-20x of the industry. The premium valuation is justified, given the scale of operations of the big players
- Public market valuation has dropped significantly from the previous high of 29.0x seen in Feb-25
- The valuation decline is primarily a function of the normalisation story (post-COVID, biotech funding decline, insourcing) with the Iran war adding a recent acute layer.

M&A Transaction multiples should also follow a similar trend and could make some transactions available at a cheaper valuation

Source: Capital IQ

Transaction Comps – Which Process Commands Premium?

Biologics and Development Focus commands premiums due to complexity and strategic value add



Bio CDMO Activities:

API: Manufacturing of the active drug substance (core therapeutic ingredient)
FDF: Formulation of the final drug product (tablet, injection, etc.) ready for patient use
CRO: Contract research services supporting drug discovery and clinical trials
Device / Packaging: Production of delivery systems (e.g., syringes) and drug packaging solutions
Biologic: Manufacturing of complex biologic drugs (e.g., antibodies, cell/gene therapies)
Development Focus: Emphasis on early-stage R&D, process development, and scaling before commercialisation

Key Observations

- Biologics command the highest multiples (25.0x EV/EBITDA) driven by complexity, high barriers to entry, and strong demand for capacity
- Development-focused CDMOs trade at 23.0x despite smaller deal sizes (~EUR 300mn), reflecting the strategic value of early-stage pipeline access
- CROs have attracted the largest deals (~EUR 2.8bn avg.) but at moderate multiples (16.5x), reflecting scale-driven consolidation dynamics
- FDF and Device/Packaging cluster in the mid-range (14.0x–16.4x), with valuations driven by specialization and IP-protected formulations
- *API transaction multiples are less meaningful due to small sample size

Source: Goldman, Jefferies, SP2 Analytics

What Lies Ahead For the Industry?

Industry Outlook: The Next Growth Phase for Bio CDMOs

Structural tailwinds and high entry barriers favor scaled global players

- The Bio CDMO sector is entering a new growth cycle with demand projected to expand at **~10% CAGR through 2030**, significantly outpacing overall pharmaceutical industry growth.
- Pharmaceutical companies are shifting from **project-based outsourcing to long-term strategic partnerships**, positioning CDMOs as critical extensions of global drug development and manufacturing supply chains while increasing customer stickiness.
- Upcoming patent expirations of blockbuster biologics such as **Keytruda and Opdivo** are expected to expand the biosimilar market significantly, increasing demand for large-scale manufacturing.
- Regulatory developments such as the **BIOSECURE Act** are accelerating a shift away from Chinese manufacturing capacity toward **Western, Japanese, and Korean CDMOs,** and may force companies like WuXi Biologics to expand outside China.
- The acquisition of Catalent by Novo Holdings highlights a growing trend of pharma companies acquiring CDMOs to secure manufacturing capacity for high-demand drugs, making companies such as **Recipharm and Curia (currently PE owned)** potential acquisition targets for strategic buyers.
- Key risk factors to our thesis are tariffs and the Middle East conflict. **Tariffs introduced in 2025** reached as high as 245% on Chinese API, imports are sharply increasing input and equipment costs, driving COGS inflation, margin pressure for Bio CDMOs under fixed-price contracts, and supply chain diversification through near-shoring, friend-shoring, and onshoring strategies. Also, the **U.S.–Iran conflict** is disrupting key **Middle Eastern logistics routes**, increasing transport costs and delays for temperature-sensitive biologics, which raises operational risks for Bio CDMOs and pushes the industry toward more diversified and resilient supply chains.

Source: Alphasense, Jefferies

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Website: www.sp2analytics.com

Email: sid.dongre@sp2analytics.com

Phone: +91-8983333940

LinkedIn: CA Siddhartha Dongre (CEO: SP2 Analytics)

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