BOURNE
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CDMO Market Update

Perspectives and Research on Biopharma Manufacturing

March 2025

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John Chiminski
Bourne Partners Senior Advisor and Former Chairman and Chief Executive Officer of Catalent

"After years of broadening their capabilities to serve as one-stop-shops for diverse biopharma needs, CDMOs are now embracing specialization to overcome the complexities of vast networks and the challenges of excelling in every area…

"This strategic shift allows them to focus deeply on advanced therapies, positioning themselves as indispensable partners in delivering cutting-edge treatments."

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Todd Bokus

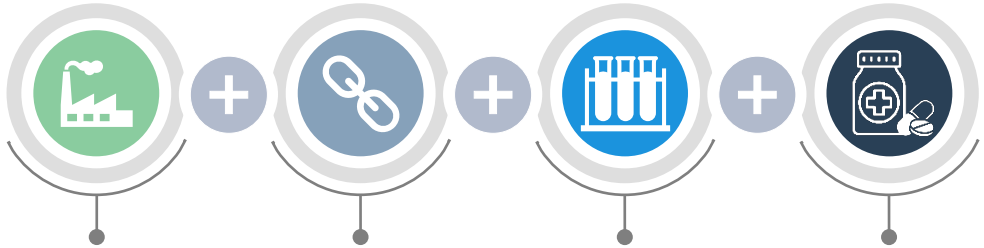
Director, Pharma Services

18 years of healthcare investment banking, with experience leading transactions across multiple pharma services subsectors

Leads pharma services coverage and execution with a focus on CDMO's and related supply chain services

BS, University of North Carolina at Charlotte

Sector Expertise



Select Transaction Experience

Afton Scientific has sold a majority stake to ACP	PROJECT FARMA a subsidiary of PRECISION MEDICINE GROUP a portfolio company of Blackstone has been acquired by PerkinElmer a portfolio company of NMC New Mountain Capital	alcami a portfolio company of MDP has acquired Masy BioServices Raising the Bar for Excellence	SUMMIT BIOSCIENCES INC. has been acquired by Kindeva DRUG DELIVERY a portfolio company of ALTARIS
TAPEMARK has been acquired by LTS TRANSDERMAL. MARKETLEADER.	AVISTA PHARMA has been acquired by Cambrex	CARLYLE GTCR has acquired amri Complex Science. Expert Solutions.	American Injectables has received growth financing from NEW RHEIN HEALTHCARE INVESTORS

FOUR (4) Key Take-Aways on the CDMO Space

We view the contract development manufacturing organization (CDMO) space as one of the most exciting growth verticals in pharma services. In particular, the rise of new precision medicines is reshaping the CDMO competitive landscape and refocusing the consolidation strategies of many of the CDMO executives and private equity investors that we talk to. We see opportunities for forward-looking CDMOs to position themselves as early market leaders in emerging, high-growth verticals such as antibody drug conjugates (ADCs), radiopharmaceutical drugs, and cell/gene-based therapies.

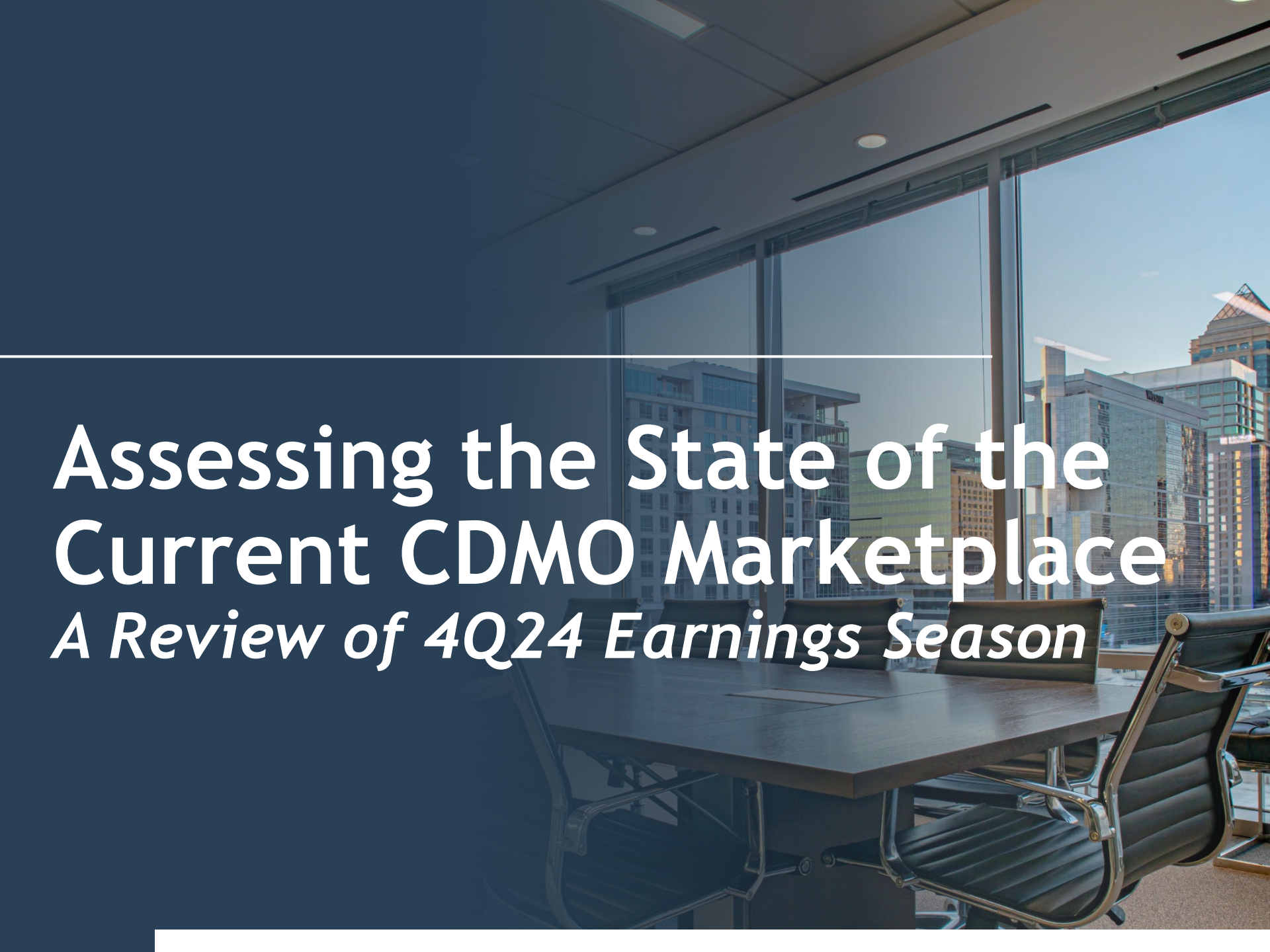
1 **Improving Prospects for the Broader CDMO Space.** We have been hearing more and more optimism from our private equity-backed CDMO relationships in recent months. A recovering biopharma funding environment should translate to opportunities for CDMOs, particularly for those partnering with small/mid-sized biopharma firms that do not typically have in-house manufacturing themselves and are more reliant on third-party CDMOs. Also, we think there is a premium on domestic manufacturing infrastructure given heightened global trade tensions with countries like China, Canada, and Mexico.

2 **Focusing on Precision Medicine.** While GLP-1 drugs manufactured by bellwether pharma companies have captured much of the media limelight in recent years, forward-looking CDMO executives are telling us that they are increasingly considering opportunities in emerging precision medicines, many of which are pioneered by smaller biotech firms. We expect outsized growth for CDMOs who can successfully position themselves in these emerging/high-growth medicines.

3 **Need for CDMO Specialization.** Over time, with the rise of precision medicine, we see specialization becoming a competitive necessity for CDMOs in a way that had not been the case in the past. Traditional CDMO manufacturing infrastructure is often poorly suited to meet the small-scale/customized production requirements of precision medicines, in our opinion. Also, the manufacturing of precision medicines often requires greater collaboration with sponsors, suppliers, and regulators.

4 **Targeted Acquisition Strategies.** In the past, much of the consolidation in the CDMO space has been around the vision of creating a “one-stop-shop.” However, as biopharma manufacturing gets more specific, manufacturing one type of medicine is not necessarily synergistic with that of other medicines, even if the CDMO shares the same customers. Now, we are hearing more conversations about consolidation strategies focused on specific drug modalities and categories. “Specialist CDMOs” have the potential to become a new category of competition -- between the mega-CDMOs and the niche CDMOs.

Source: Bourne Partners



Assessing the State of the Current CDMO Marketplace

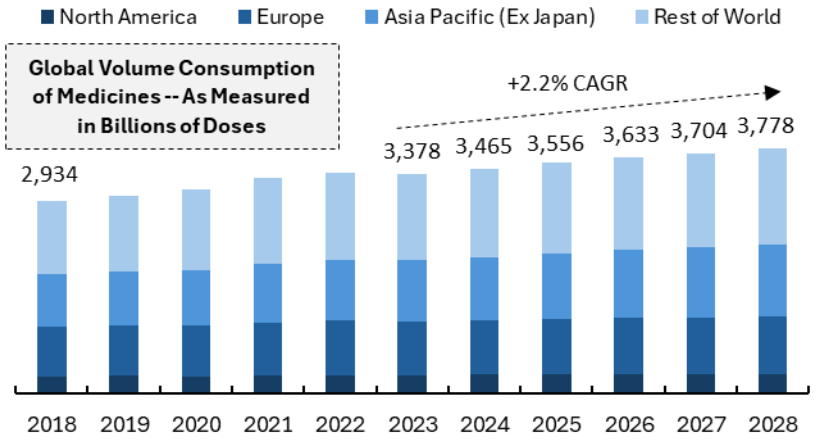
A Review of 4Q24 Earnings Season

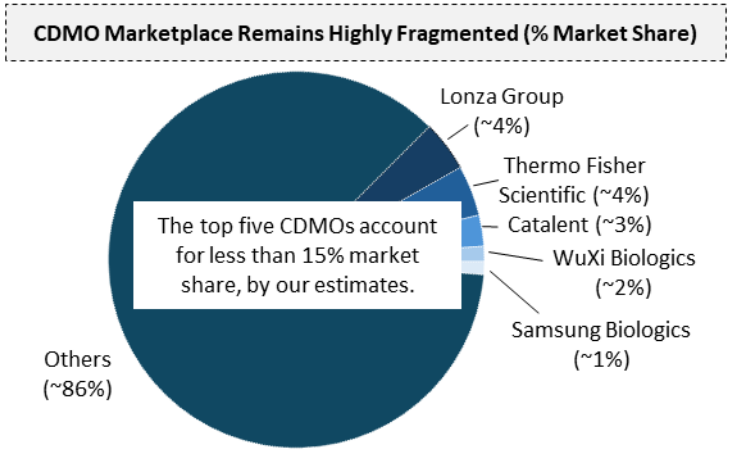
Our Take on the State of the Global CDMO Marketplace

We model the global CDMO marketplace to reach ~$200 billion of revenues in 2025 with mid/high single digit growth thereafter. Outsourcing to CDMOs has increased significantly over the past decade, and, today, a majority of biopharma firms outsource both their small and large molecule drug manufacturing to third-party CDMOs.

The value proposition of a CDMO is as strong as ever, in our view. In a capitally constrained environment, biopharma companies need to focus their resources on core competencies, while outsourcing non-core activities, such as manufacturing, as a 'shared service' to third-parties. The benefits of outsourcing to a CDMO are well established -- to lower production costs, accelerate drug development and commercialization, improve regulatory compliance, and access niche manufacturing infrastructure.

However, **the marketplace for CDMOs is still very fragmented and heterogeneous.** By our analysis, the top five CDMOs currently account for less than 15% market share, in aggregate. Given the demonstrable benefits of economies of scale, we see a long runway of CDMO consolidation in the years ahead -- with larger CDMOs strategically acquiring smaller CDMOs to create integrated, end-to-end capabilities for their pharma customers. Also, we expect to see more consolidation around specific categories of precision medicine, each of which requires specialized expertise and production infrastructure.





Source: The IQVIA Institute, Company reports, and Bourne Partners

Post-Mortem for 2024: Better Times Ahead

Exiting the 4Q24 earnings season, **we view the CDMO space as (finally) set up for reaccelerating growth in 2025 and 2026** after struggling through the wind down of COVID-19 projects, capital market pressures on small/mid-sized biopharma sponsors, and weak economic conditions for consumer-related businesses in 2023 and 2024. Underlying these macro pressures was consistently strong demand for the manufacturing of biologic and precision medicines.

Lonza

Lonza (SWX:LONN) is projecting low teens revenue growth at its "core CDMO" business in 2025 with growth expected to accelerate as the year progresses. Management highlighted that an uptick in the macro biotech funding environment from 2023 to 2024 is translating to more opportunities for Lonza in 2025. Overall revenues declined modestly in 2024. However, demand was otherwise very strong for its biologics business (e.g., mammalian and bioconjugates). Also, revenues from cell and gene-based therapies grew 10% in 2024, excluding the lingering impact of a major project termination with Moderna (announced in late 2023).

Thermo SCIENTIFIC

Thermo Fisher Scientific (NYSE:TMO) continues to target a 7%-9% long-term consolidated organic revenue growth rate -- driven disproportionately by its "services" businesses, including its CDMO. Disclosures on its CDMO business are limited; however, the company commented that its CDMO results were impacted by weak capital markets as well as the winddown of COVID-19 activity. In our view, management appeared optimistic that its CDMO revenue growth would return to "normal" levels in 2026.

Catalent

Visibility to financial trends at Catalent has become obfuscated since being taken private by Novo Holdings in December 2024. A review of Catalent's SEC filings suggests that growth has been pressured throughout calendar 2024 similar to other CDMOs. However, in our view, there were some signs of recovery in the second half of the year with respect to its gene therapy business, including its expanded partnership with Sarepta Therapeutics (NASDAQ: SRPT), and its orally disintegrating Zydis product offerings.

药明康德 WuXi AppTec

WuXi Apptec (OTCMKTS: WUXAY) and WuXi Biologics (OTCMKTS: WXXWY) have both downplayed the impact of the BIOSECURE Act (and the election of Trump) with reportedly "limited" impact on their respective 2024 results. In fact, excluding COVID-19 related business, both WuXi AppTec and WuXi Biologics have recently forecasted near-10% revenue growth in 2025.

SAMSUNG BIOLOGICS

Samsung Biologics has been a standout performer in the CDMO space with 20%+ revenue growth in 2024 and guidance for 20%+ revenue growth in 2025 as well. Notably, Samsung Biologics won three $1 billion-plus contracts over the past year and, today, the company now has contracts with 17 of the top 20 global pharma companies and 110 pharma companies overall.

Source: Company reports and Bourne Partners

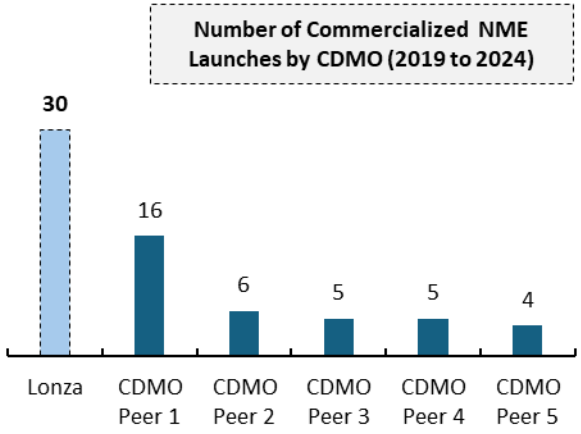
Lonza: Restructuring into a "Pure Play" CDMO

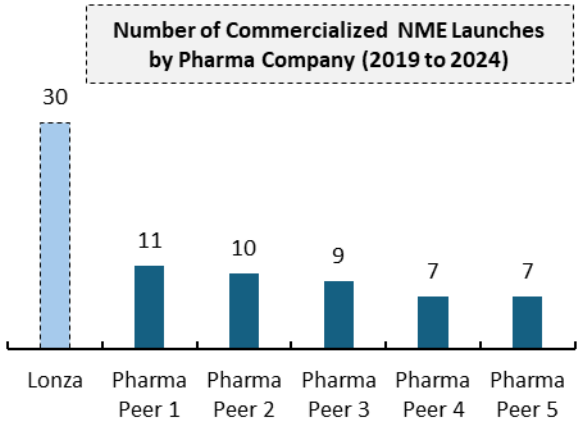
In July 2024, **Lonza recruited a new Chief Executive Officer who immediately put into process a plan to remake Lonza into a pure-play CDMO.** A new operating structure is expected to be rolled out imminently. Altogether, this is designed to position Lonza for 10%+ revenue growth with a platform that should be more supportive of targeted acquisitions.

In December 2024, **Lonza formally unveiled its "One Lonza" restructuring strategy, under which it will reorganize its businesses**, streamline its operations, and shed non-core assets. Most notably, this includes plans to exit the "Capsules and Health Ingredients" business unit at some "appropriate time" in the future. Management has commented that this is not a traditional CDMO business, so it is not an area that fits into Lonza's vision of becoming a more focused "pure play" global CDMO. Also, revenues at the Capsules and Health Ingredients business have underperformed in 2024 due to generally weak demand (as well as inventory destocking).

Separately, to keep pace with strong demand for large molecule drugs, in October 2024, **Lonza acquired one of the largest biologics manufacturing facilities in the world from Roche for $1.2 billion**. This materially increases Lonza's large-scale biologics capacity with 330,000 additional liters of incremental bioreactor capacity for mammalian therapies. Also, this gives Lonza a presence on the West Coast of the United States (Vacaville, California), complementing Lonza's existing biologics manufacturing on the East Coast.

Lonza is the Largest Global CDMO / Manufacturer of Pharma Products as Measured by Commercialized Drug Approvals





Number of Molecules in Development at Lonza (e.g., Preclinical and Clinical Phase I-IV)

~900

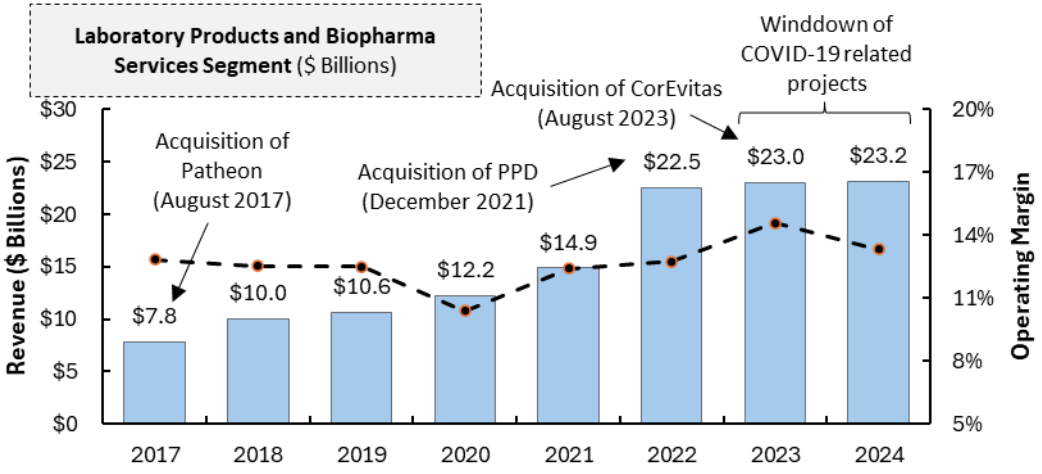
Source: Lonza and Bourne Partners

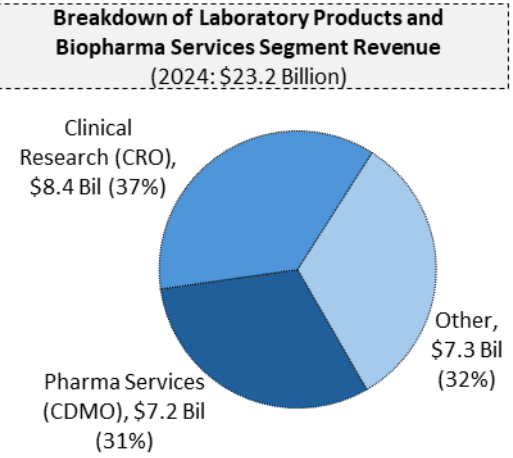
Thermo Fisher Scientific: CDMO + CRO

Thermo Fisher is a life sciences conglomerate with $42.9 billion of consolidated revenue, including a CDMO and CRO business with ~$7 billion and ~$8 billion of annual revenue, respectively. Most notably, Thermo Fisher recently launched a new service model that integrates its CRO and CDMO services into a single outsourcing solution for customers.

In late 2024, Thermo Fisher announced its "Accelerator Drug Development" solution, which integrates its CRO and CDMO services into a "single outsourcing option." This is something worth watching, in our view, since it is a major attempt to bring together a clinical-phase CRO and a global-scale CDMO under one roof. Traditionally, these services have been procured separately. However, with the rising focus on precision medicines, management hopes that this combination will allow Thermo Fisher to be able to offer its pharma and biotech customers more streamlined execution and greater visibility into their product development.

Thermo Fisher considers itself as a global leader in sterile fill finish services and clinical trial supplies and logistics. In our view, this positions Thermo Fisher to benefit from an elevated mix of complex and biologic drugs that require an intravenous, intramuscular, and/or subcutaneous injection (and fill finish services). Also, Thermo Fisher should benefit from Catalent being acquired by Novo Holdings since this is expected to take considerable competitive sterile fill-finish capacity off the market.





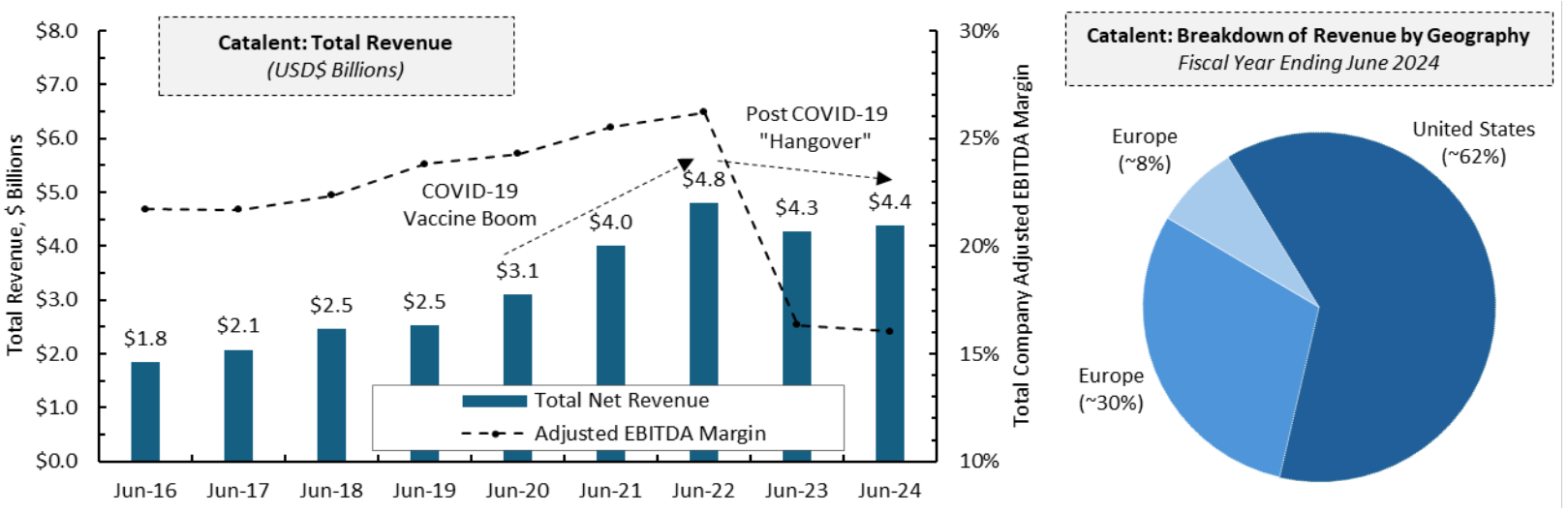
Source: Thermo Fisher Scientific and Bourne Partners

Catalent: Under New Ownership

Novo Holdings, the new owner of Catalent, has been in the press recently discussing its plans to double the size of Catalent over the next five years. In our view, this may include facility expansions and acquisitions in North America to prepare Catalent to support policy efforts by the Trump administration to onshore more pharma manufacturing.

The December 2024 closing of the $16.5 billion mega-acquisition of Catalent by Novo Holdings, also the controlling shareholder of Novo Nordisk (NOVOb.CO), has generated mixed viewpoints about how it may (or may not) impact the broader CDMO space. Some are concerned that it may limit competition given that three of Catalent's fill-finish facilities were subsequently sold to Novo Nordisk to support the production of GLP-1 drugs. Also, over time, Catalent will likely become a captive, in-house manufacturing platform for upwards of 90 biopharma assets that are currently being held by Novo Holdings.

Looking ahead, **we expect Catalent will benefit from any protectionist trade policies by the U.S. government**, including recently threatened (and imposed) tariffs on Chinese, Mexican, and Canadian pharma imports by the Trump administration. Today, Catalent generates 90%+ of its revenues in the U.S. or Europe based on local manufacturing facilities with only one site in China (Shanghai).



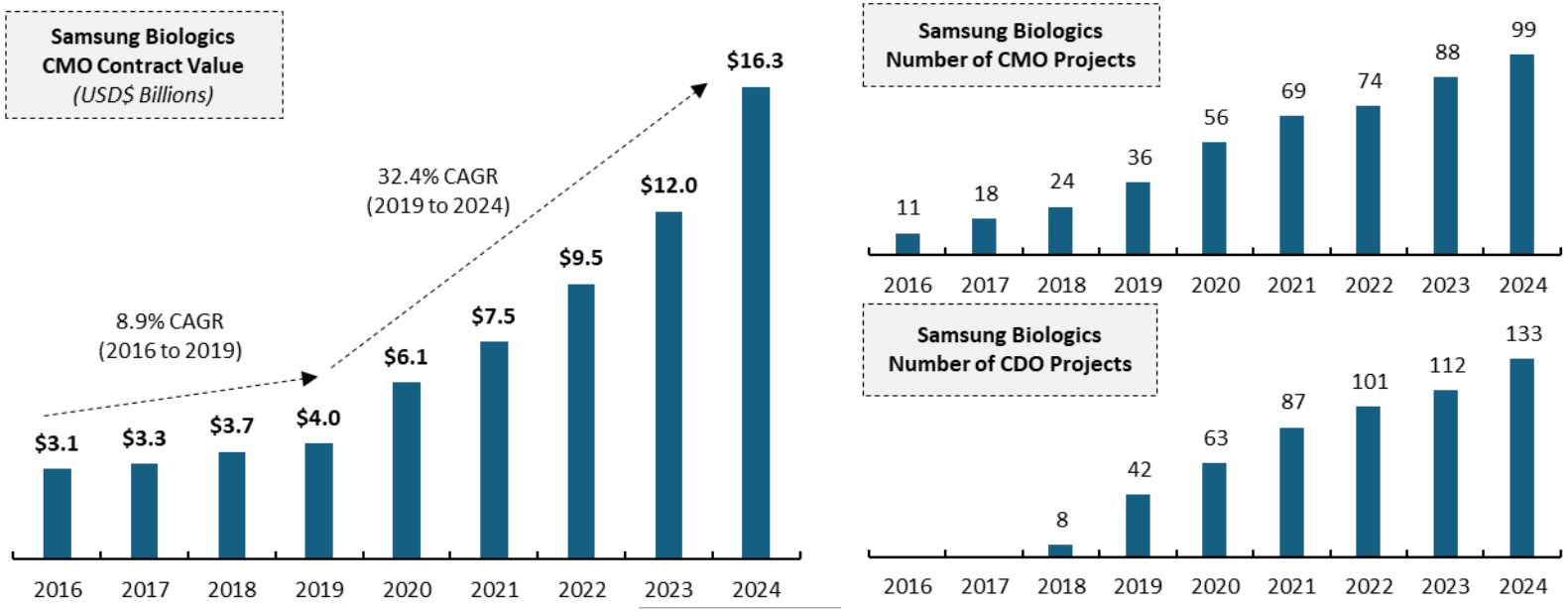
Source: Catalent and Bourne Partners

Samsung Biologics: Making Moves into the ADC Space

Samsung Biologics has been a standout performer in the CDMO space over the past year during an otherwise difficult post-COVID period. Most notably, Samsung Biologics won three $1 billion-plus multi-year contracts in the second half of 2024. This contributed to 35%+ growth of contract value in 2024, following three consecutive years of 20%+ growth.

In early 2025, Samsung Biologics made a big move into the antibody-drug conjugate (ADC) space with the completion of a new 500-liter ADC-dedicated production facility in Songho, Incheon, South Korea. This new facility will house an expanded collaboration with LigaChem Biosciences to support a series of ADC development programs.

This state-of-the-art ADC facility is designed to support diverse batch sizes with fully customizable and disposable containment systems, and it is expected to leverage Samsung Biologics's existing expertise in monoclonal antibody CDMO services. Samsung Biologics claims to have the leading production capacity for antibody therapeutics, totaling over 600,000 liters.



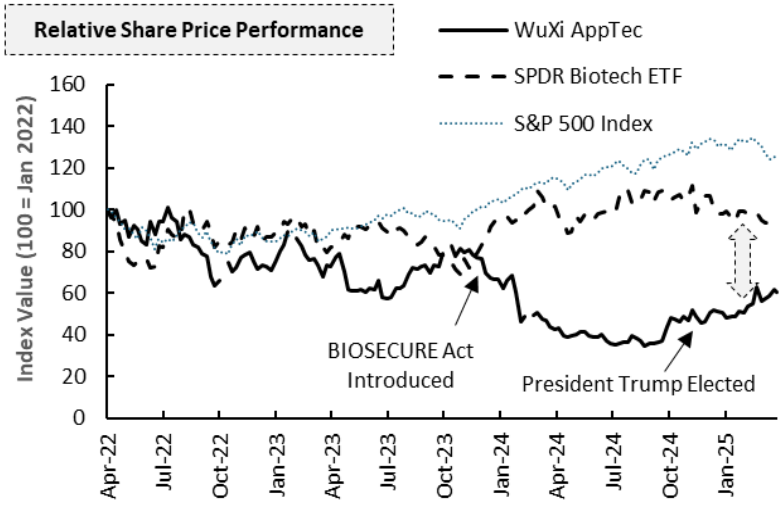
Source: Samsung Biologics and Bourne Partners

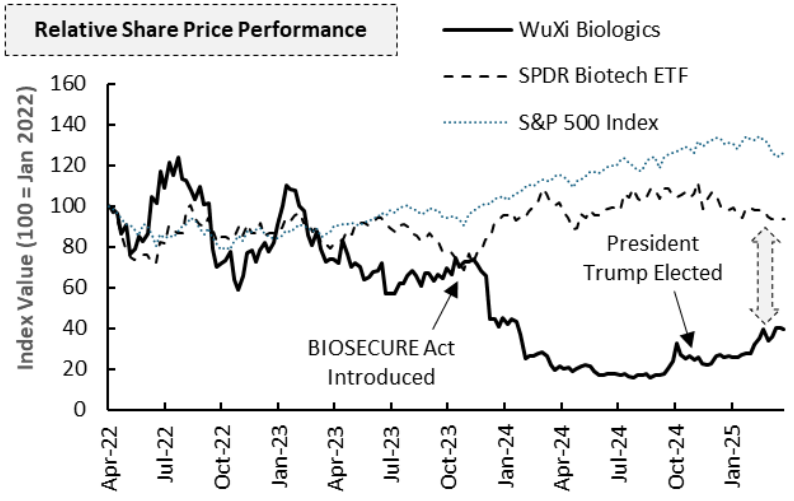
WuXi: Under the Shadow of Trump and BIOSECURE

There is much industry focus on how Chinese sister companies WuXi Apptec and WuXi Biologics will be impacted by any potential protectionist policies of the new President Trump administration, including the recently imposed tariffs on pharma imports from China and/or any potential reintroduction of the BIOSECURE Act (or something similar).

Both WuXi Apptec and WuXi Biologics have seen very strong financial performance over the past decade. In our view, there is yet to be any visible impact of the introduction of the BIOSECURE Act and/or the election of President Trump on the financial results of either company. However, contracting/sales cycles are very long in the CDMO space so it will take time (years) for the effect of any incremental protectionist policies by the U.S. government to show up in financial results.

Investors reacted immediately to the introduction of the BIOSECURE Act in the autumn of 2023, and the market clearly remains concerned about the geopolitical environment. Most of the revenue of both of these Chinese companies are generated in the United States. Today, the share prices of WuXi AppTec and WuXi Biologics are down 40% and 60%, respectively, since early 2022 -- very significantly underperforming the broader stock market (S&P 500; up 27%) and the biopharma sector (SPDR biotech ETF; down 7%).





Note: Market values as of the close of business March 25, 2025.
Source: S&P Global Market Intelligence, Wuxi AppTec, Wuxi Biologics, and Bourne Partners

Macro Factors Impacting CDMO Growth Trends

Key Macro Factors Impacting CDMO Growth Trends

Outside of the publicly traded CDMOs, **we have been hearing more and more optimism from our private equity-backed CDMO relationships** in recent months, and this is consistent with various outside surveys. One recent survey by CPHI Milan showed that ~49% of executives expect improving growth over the next 18 months (vs only 7% who were negative).

1) Improving Funding Environment for Drug Development

We think that CDMOs should benefit from a recovering biopharma funding environment. In particular, this should provide a boost for small/mid-sized biopharma sponsors, many of which do not have in-house drug manufacturing infrastructure.

2) Greater Focus on Specialized Precision Medicines

Advances in molecular biology are leading to new precision medicines targeting niche patient populations. This includes antibody drug conjugates, radiopharmaceutical drugs, and cell and gene therapies, among many others. These new precision medicines typically require specialized manufacturing facilities, equipment, and processes that can be scaled up and down on short notice.

3) Increasing Mix of Injectable/Infusion Drugs Driving Need for "Fill Finish" Capacity

There is an increasing mix of biologic drugs coming to market that require intravenous, intramuscular, and/or subcutaneous administration. This requires "fill finish" manufacturing, which is a function that is commonly outsourced to CDMOs.

4) Demand for GLP-1 Drugs Crowding Out Existing Production Capacity

The surging demand for GLP-1 drugs is crowding-out CDMO manufacturing capacity, particularly related to fill finish services. In our view, this dynamic may be exacerbated by Catalent selling three of its fill/finish facilities to Novo Nordisk in late 2024.

5) On/Friend-Shoring of Production and Supply Chain

Pharma and biotech companies are re-evaluating their CDMO and supply chain relationships in light of President Trump's willingness to implement sizable tariffs on imports from countries like China, Canada, and Mexico. Also, a potential re-emergence of the BIOSECURE Act (or something similar under President Trump) could drive significant focus to domestic manufacturing.

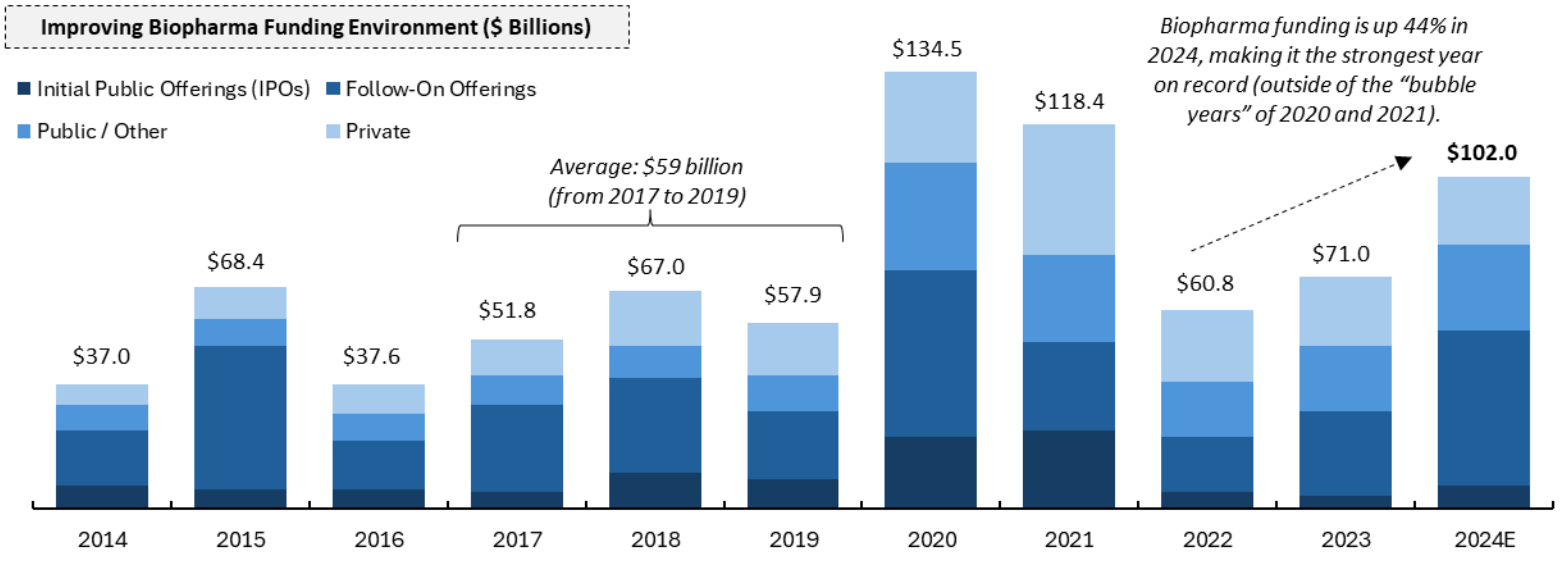
Source: Bourne Partners

Improving Biopharma Funding Bodes Well for CDMOs

We view an improving biopharma funding environment as a positive leading mid/long-term indicator for demand for outsourced manufacturing. In our view, there tends to be a 12-to-24-month time lag between a funding event and the launch of a new clinical trial. Accordingly, we think that the improvement in the biopharma funding environment in 2023 and 2024 bodes well for increasing demand for CDMOs in 2025 and 2026 (and beyond).

Biopharma financings exceeded $102 billion in 2024, according to BioWorld, despite a sluggish end to the year. This is the third highest year on record -- behind only the "bubble years" of 2020 and 2021. In total, 2024 financings were up 44% year-over-year (versus $71 billion in 2023) and up 71% from pre-COVID levels (versus the annual average of $59 billion in 2017, 2018, and 2019).

The top four disease areas (oncology, immunology, metabolic/endocrinology, and neurology) accounted for 79% of clinical trial starts over the past year. Much of the new funding is geared towards precision medicines in oncology and rare diseases -- as well as new unmet disease areas in Alzheimer's Disease, central nervous system (CNS) disorders, and metabolics (GLP-1 drugs).



Source: Bioworld Report, IQVIA Investor Day (December 2024), and Bourne Partners

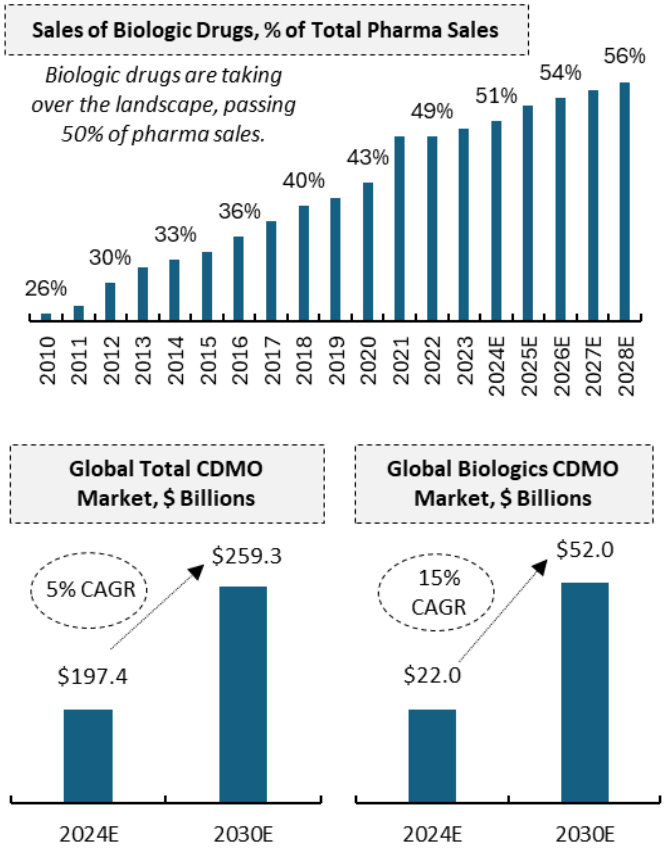
Mix Shift Towards Complex and Biologic Medicines

The majority (~80%) of CDMO demand comes from the production of small molecule drugs. However, **a disproportionate amount of the *growth* for CDMOs will come from large molecule biologic drugs**, in our view. We estimate that global biologic CDMO revenues are upwards of $20 billion with growth in the ~mid-teens through the rest of the decade.

Large molecule biologic drugs now account for over half of total global pharma spending -- up from about a third a decade ago. This percentage is expected to continue to grow in the coming years given that we believe most of the new drugs in development are biologics. In many ways, biologics are superior to small molecule drugs since they can be designed to target specific cells, which makes them more efficacious and mitigates side effects. This mix shift has significant implications for CDMOs.

Notably, **biologic drugs are much more complex to manufacture**, often requiring dedicated facilities and equipment, skilled staff, and specialized processes -- as well as unique regulatory considerations. Specifically, biologics are made from large molecules with anywhere from 3,000 to over 25,000 atoms -- considerably larger than small molecule drugs. Also, rather than being synthesized with chemicals, biologic drugs consist of a variety of organic materials, such as sugars, proteins, and nucleic acids, and they are made from cells, tissues, and other living organisms.

Moreover, **the heterogeneity of biologic drugs results in opportunities for CDMOs to specialize.** For instance, there are mammalian cell CDMOs, microbial fermentation CDMOs, gene therapy CDMOs, cell therapy CDMOs, and vaccine CDMOs. It is unusual for pharma companies to have these specialized biologic manufacturing capabilities in-house.



Source: Evaluate Pharma, Precedence Research, and Bourne Partners

Biosimilars As a Potential Accelerant to Biologic CDMOs

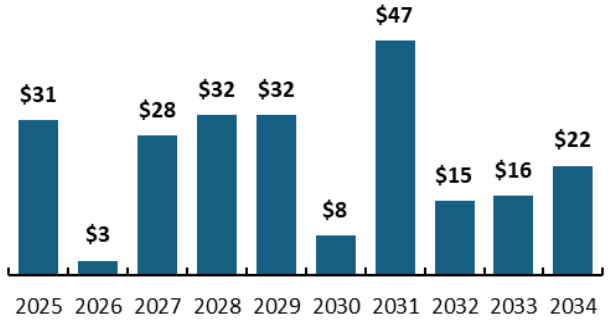
We see the potential emergence of biosimilars as an accelerant to the need for more CDMO biologic manufacturing capacity, particularly in the United States. Domestic demand for biosimilars remains frustratingly low. However, there are numerous policy actions underway to encourage the acceptance and use of biosimilars in the coming years.

Encouraging the use of biosimilars has been a focus of policymakers for years given the potential for material cost savings. Various studies suggest that pricing on a biologic drug can drop by as much as 15% to 35% in the presence of a biosimilar alternative. Yet, in the United States, the use of biosimilars remains stubbornly low due to a lack of trust by physicians and patients that biosimilars can equal the original biologic counterparts. Also, some argue that that the use of rebates by pharma companies and PBMs have perversely incentivized the use of higher-priced branded biologic drugs.

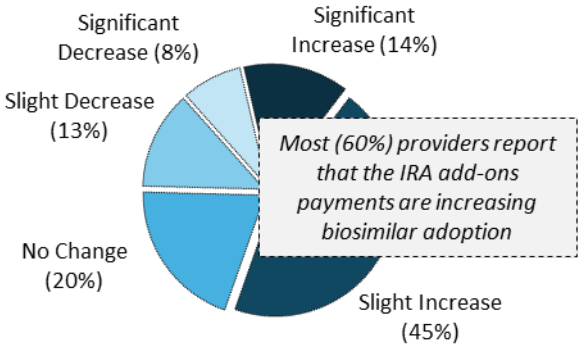
Looking ahead, **we see a significant window of opportunity for biosimilars over the next decade** with 118 biologics, representing $232 billion in annual U.S. sales, facing patent expiry. To address this, the U.S. Food and Drug Administration (FDA) has funded educational and outreach programs to educate physicians and patients on the clinical efficacy of biosimilars.

Also, **the *Inflation Reduction Act* (IRA) of 2022 gave premium Medicare Part B reimbursement for biosimilars** at 108% ASP (vs 106% in the past). Recent survey data suggests that this premium reimbursement is starting to have a positive impact with 59% of providers in one survey saying that it has resulted in a "significant" or "slight" increase in adoption. Also, a strong majority of providers expect biosimilar utilization will increase over the next five years with the IRA incentives being a major factor behind this increase.

Opportunity for Biosimilars? Biologic Patient Expiries Over the Next Decade, as Measured by Sales in the Year Prior, $ Bils)



Impact of IRA Add-On Payments on Biosimilar Utilization



Source: U.S. Food and Drug Administration (FDA), the IQVIA Institute ("Assessing the Biosimilar Void in the U.S.", February 2025), and Bourne Partners

The Rising Influence of Precision Medicine

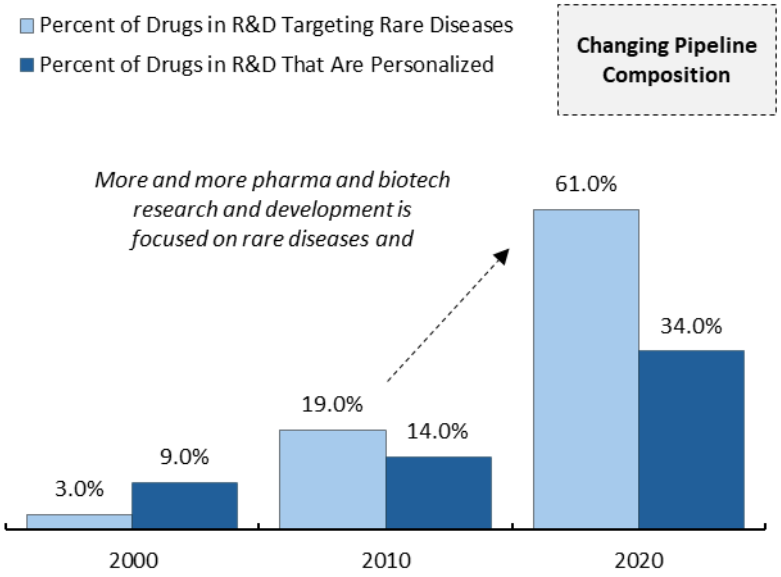
The use of biologics (and biosimilars) has facilitated the rise of precision medicine, i.e., the tailoring of drugs towards specific targeted populations and rare diseases. This has significant ramifications for the CDMO space given that precision medicine implies the need for small-batch manufacturing, specialized facilities and equipment, and unique expertise.

Precision medicine refers to the use of targeted medications based on a patient's genetics as well as environmental and lifestyle factors. This includes antibody drug conjugates, radiopharmaceuticals, and cell/gene therapies, among other categories of drugs.

Precision medicine requires the ability to execute small batch manufacturing of complex drugs. Many large pharma companies do not have the technical expertise to manufacture complex precision medicines in-house. Also, the small batch (sub-scale) nature of the production of these medicines often makes it financially unviable for an individual pharma company to produce. Applying the legacy model of single-product lines to precision medicine manufacturing can lead to idle time and equipment (and wasted resources).

CDMOs, in turn, need to be flexible in their approach to supporting precision medicine production including an ability (and willingness) to adapt to changing circumstances. This can be challenging for larger CDMOs that often have a number of competing projects and areas of operational focus.

The manufacturing of precision medicines requires specialized facilities and equipment to seamlessly transition through clinical development to commercial production. Adding to this, the production of precision medicines includes specialized expertise, such as analytical and biopharma testing, lyophilization capabilities, sterile fill-finish/aseptic processing, and highly potent compound handling. This often requires multiple CDMOs since it is unlikely that a single CDMO (or pharma company) would have all of these capabilities in-house.



Source: Tufts Center for the Study of Drug Development, and Bourne Partners

Trend Towards Injectable Medicines

More and more drug approvals by the U.S. Food and Drug Administration (FDA) consist of injectables, by our analysis. This is a natural consequence of the increasing mix of biologic drugs and the focus on precision medicine. By our analysis, since January 2021, 92 of the 192 (or 47.9%) of the new molecular entity (NME) approvals by the FDA were for drugs that require an intravenous, intramuscular, and/or subcutaneous injection. This percentage is likely to continue to grow in the coming years given that almost two-thirds of new drugs in development are large molecule biologics.

New Molecular Entity (NME) Approvals By the U.S. Food and Drug Administration (FDA)

Total Drugs Approved: 50 *Injectables: 24 (48.0%)*		
NME Approvals: 2021 *January to December*		
Adbry	Bylvay	Fotivda
Leqvio	Rezurock	Azstarys
Vyvgart	Fexinidazole	Pepaxto
Tezspire	Kerendia	Nulibry
Cytalux	Rylaze	Amondys 45
Livtencity	Aduhelm	Cosela
Voxzogo	Brexafemme	Evkeeza
Besremi	Lybalvi	Ukoniq
Scemblix	Truseltiq	Tepmetko
Tavneos	Lumakras	Lupkynis
Livmarli	Pylarify	Cabenuva
Qulipta	Rybrevant	Verquvo
Tivdak	Empaveli	
Exkivity	Zynlonta	
Skytrofa	Jemperli	
Korsuva	Nextstellis	
Welireg	Qelbree	
Nexviazyme	Zegalogue	
Saphnelo	Ponvory	

Total Drugs Approved: 37 *Injectables: 18 (48.6%)*	
NME Approvals: 2022 *January to December*	
NexoBrid	Spevigo
Briumvi	Xenpozyme
Xenoview	Amvuttra
Lunsumio	Vtama
Sunlenca	Mounjaro
Krazati	Voquezna
Rezlidhia	Camzyos
Tzield	Vivjoa
Elahere	Pluvicto
Tecvayli	Opdualag
Imjudo	Ztalmy
Lytgobi	Vonjo
Relyvrio	Pyrukynd
Omlonti	Enjaymo
Elucirem	Vabysmo
Terlivaz	Kimmtrak
Rolvedon	Cibinqo
Sotyktu	Quviviq
Daxxify	

Total Drugs Approved: 55 *Injectables: 25 (45.5%)*		
NME Approvals: 2023 *January to December*		
Wainua	Aphexda	Miebo
Filsuvez	Veopoz	Veozah
Fabhalta	Sohonos	Elfabrio
Ogsiveo	Elrexfio	Qalsody
Truqap	Talvey	Joenja
Ryzneuta	Izervay	Rezzayo
Augtyro	Zurzuvae	Zynyz
Defencath	Xdemvy	Daybue
Fruzaqla	Vanflyta	Zavzpret
Loqtorzi	Beyfortus	Skyclarys
Omvoh	Ngenla	Filspari
Agamree	Rystiggo	Lamzede
Bimzelx	Litfulo	Jesduvroq
Zilbrysq	Columvi	Orserdu
Velsipity	Inpefa	Jaypirca
Rivfloza	Posluma	Brenzavvy
Pombiliti	Paxlovid	Leqembi
Exxua	Xacduro	
Ojjaara	Epkinly	

Total Drugs Approved: 50 *Injectables: 25 (50.0%)*		
NME Approvals: 2024 *January to December*		
Kisunla	Letybo	Flyrcado
Ohtuvayre	Exblifep	Cobenfy
Piasky	Zelsuvmi	Aqneursa
Sofdra	Alhemo	Miplyffa
Iqirvo	Alyftrek	Ebglyss
Rytelo	Tryngolza	Lazcluze
Imdelltra	Ensacove	Niktimvo
Xolremdi	Crenessity	Livdelzi
Ojemda	Unloxcyt	Nemluvio
Anktiva	Bizengri	Yorvipath
Lumisight	Iomervu	Voranigo
Zevtera	Rapiblyk	Leqselvi
Voydeya	Attruby	
Vafseo	Ziihera	
Winrevair	Revuforj	
Duvyzat	Orlynvah	
Tryvio	Vyloy	
Rezdiffra	Hympavzi	
Tevimbra	Itovebi	

= Drugs requiring an intravenous, intramuscular, and/or subcutaneous injection

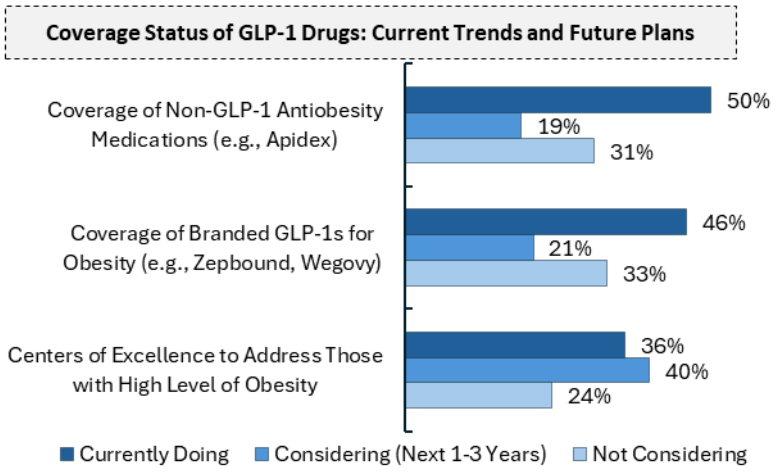
Source: U.S. Federal Drug and Food Administration and Bourne Partners

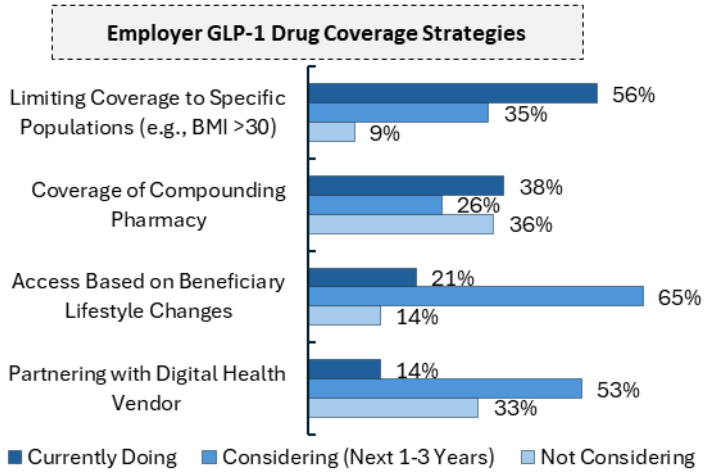
GLP-1 Drugs Crowding Out Existing CDMO Capacity

The ongoing surging demand for GLP-1 drugs is crowding-out CDMO manufacturing capacity, particularly for fill finish services. This is creating an increasingly favorable supply/demand dynamic for CDMOs in this area. This dynamic may be exacerbated in the coming years as a result of Catalent selling three of its fill/finish facilities to Novo Nordisk in late 2024.

The rapidly increasing demand for GLP-1 drugs is unlikely to slow in the near/mid-term given an increasing willingness by employers to cover these drugs for weight loss (obesity). Today, there are almost 60 million Americans with private health coverage who could be eligible for GLP-1 drugs for diabetes and/or obesity -- versus 8.2 million who are currently using them. Adding to this, as one of its last policy actions, the former President Biden administration proposed new regulation that would allow Medicare and Medicaid to cover GLP-1 drugs for obesity as well. It will be left to be seen whether President Trump will finalize this regulation.

CDMOs, in turn, are scrambling to increase their manufacturing capacity to keep pace. With CDMOs prioritizing lucrative GLP-1 contracts, the surging demand for GLP-1 drugs is leading to shortages in supply even for non-GLP drugs. To secure access to capacity, we are hearing more anecdotes about pharma companies being willing to enter into longer-term contracts with CDMOs. Also, pharma sponsors are looking for ways to diversify their CDMO relationships to mitigate dependence on any one provider.





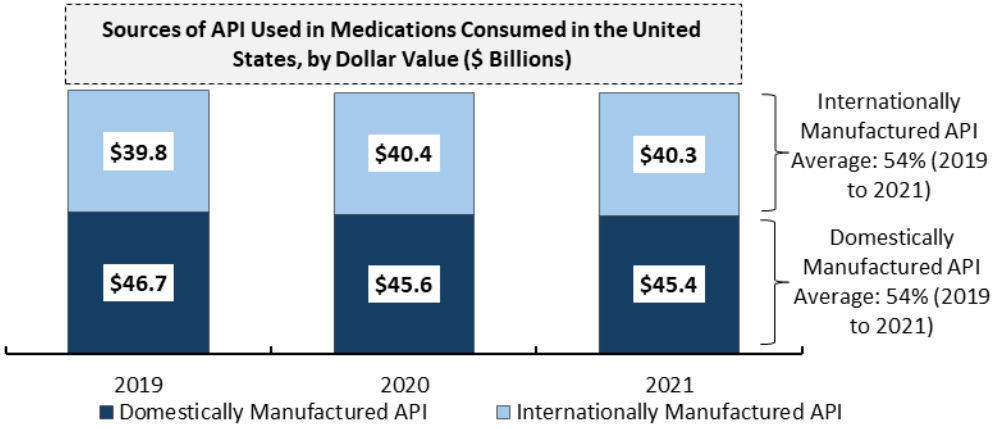
Source: Kaiser Family Foundation and Bourne Partners

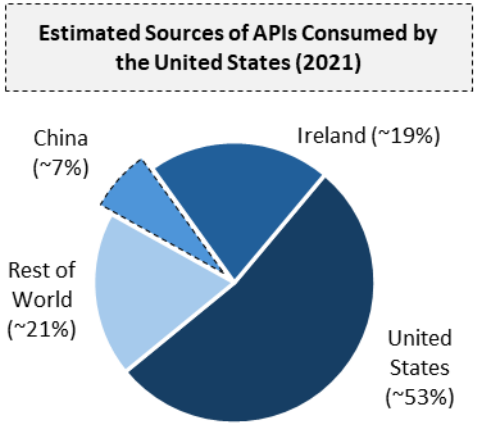
The Emerging Trade Policy of President Trump

President Trump appears relentlessly focused on rebuilding U.S. domestic pharma manufacturing -- as a matter of "national security." During his first weeks in office, Trump immediately used the authority given to him under the *International Emergency Economic Powers Act* to impose sizable tariffs on imports from Canada, China, and Mexico.

During his Presidential campaign, **Trump had indicated that he plans to aggressively use duties, tariffs, and trade policy to advance U.S. interests.** In fact, during his inauguration speech in his first day in office, Trump verbally indicated his intent to "overhaul" U.S. trade with the establishment of an "external revenue service to collect all tariffs, duties and revenues." Shortly thereafter, Trump released a memorandum directing various federal agencies to evaluate U.S. trade policy and provide formal recommendations. These recommendations are due back to Trump in April, and they may include more targeted trade restrictions on pharma imports.

In the meantime, **President Trump ordered a 10% broad-based tariff on Chinese imports (including pharma related products) in February with an additional 10% tariff imposed a month later in March.** Estimates vary, but most sources suggest China represents anywhere from 5%-15% of total pharma imports to the United States. Also, **Trump has been threatening a 25% tariff on imports from Canada and Mexico** as well. Industry groups are lobbying the Trump administration to grant "carve-outs" for pharma products and medical devices. However, commentary from Trump suggests that he is unwilling to compromise on this issue, in our opinion.





Source: Avalere Health (July 2023) and Bourne Partners

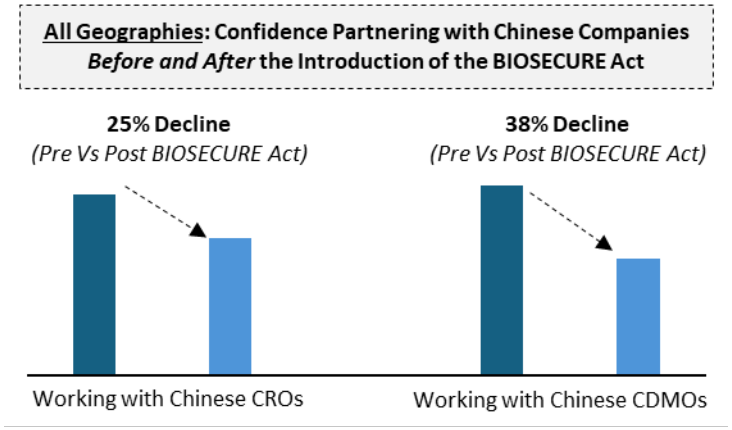
Will We See a Return of the BIOSECURE Act in 2025?

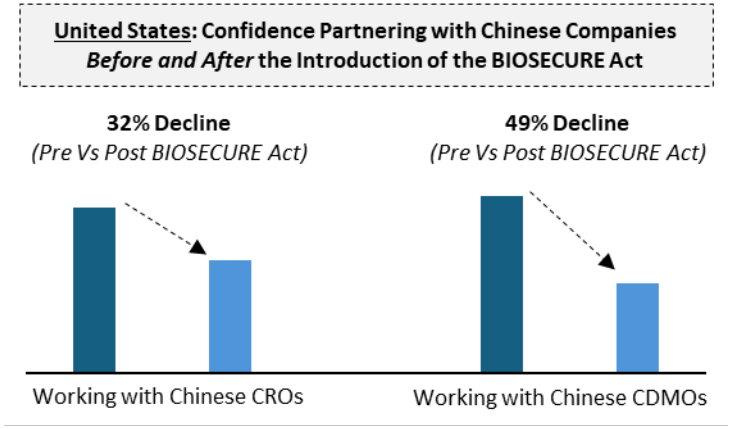
On top of tariffs, duties, and trade policy, **we see the potential for a return of the BIOSECURE Act (or some similar legislation)** in 2025. The BIOSECURE Act stalled in the Senate in late 2024. However, the legislation had strong bipartisan support, and political concerns about Chinese biotech companies remain prevalent, in our view.

Originally introduced in late 2023, **the BIOSECURE Act has significant implications on the CDMO space.** Although the BIOSECURE Act failed to pass Congress in 2024, the threat of it passing has already had its intended impact. Recent survey data suggests that life sciences companies worldwide (and in the United States especially) have become significantly less confident relying on Chinese CDMOs (vs last year).

In fact, **several major pharma companies have recently announced or suggested plans to re/onshore manufacturing capacity.** As an example, Eli Lilly and Co (NYSE: LLY) announced plans for a significant $27 billion investment in new U.S. manufacturing capacity with a focus on active pharmaceutical ingredients that are typically imported. Similarly, Pfizer (NYSE:PFE) told investors that it may bring overseas manufacturing back to the U.S. based on the trade policy of the Trump administration.

Given the long lead times need to adjust CDMO and supply chain relationships, **we continue to argue that pharma and biotech companies need to be proactively re-evaluating their CDMO and supply chain relationships now.** Today, almost half of the pharmaceuticals consumed domestically are directly produced offshore (or are based on overseas raw materials). China, in particular, accounts for anywhere from 7% to 13% of the API used in U.S. pharma end-product manufacturing, according to an analysis by Avalere Health.





Source: L.E.K. 2024 Global Survey on Impact of US BIOSECURE Act and Bourne Partners

Deep Dive Into Precision Medicine Manufacturing

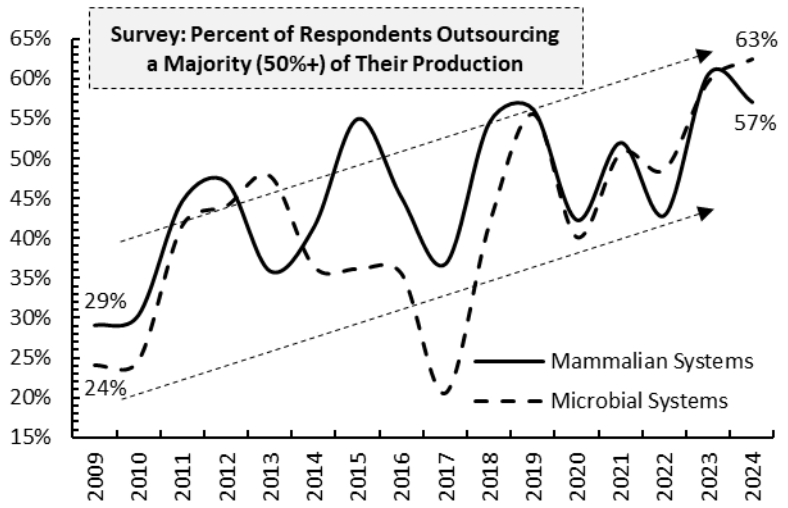
Focusing on Precision Medicine as a Key Driver of Growth

Looking ahead, **we expect a disproportionate amount of the forward growth for the CDMO space will be driven by the production of complex and biologic drugs associated with precision medicine.** Altogether, we estimate complex and biologic drugs represent $20 billion of annual production today with ~mid-teens growth through the rest of the decade.

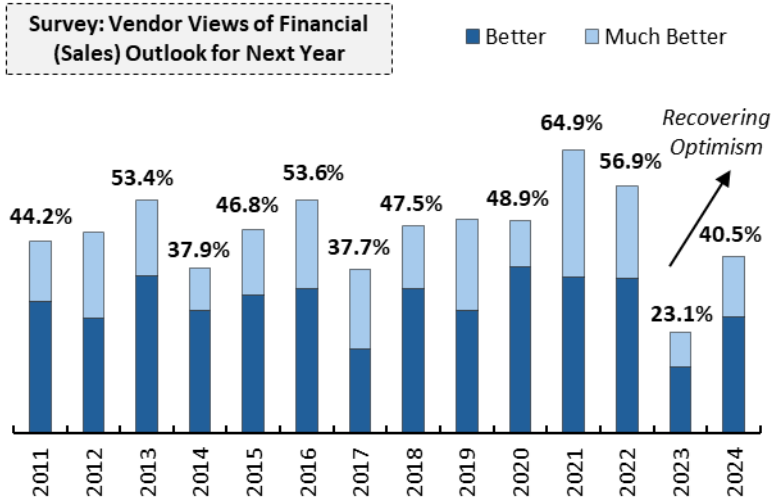
The outsourcing of complex and biologic drugs has been steadily increasing for well over a decade, as highlighted by data from *BioPlan Associates*. Mammalian cell culture systems are foundational (and a good proxy) to overall biologics manufacturing, in our opinion. Facilities outsourcing a majority (50%+) of their mammalian production has doubled from 29% in 2009 to 57% in 2024. Also, microbial systems, e.g., recombinant proteins, enzymes, and vaccines, show similar outsourcing trends, increasing from 24% to 63%.

Optimism for future outsourcing rates is rising. After a historical low point in 2023, CDMO "optimism" for growth in the coming year bounced back sharply in 2024. In 2024, 13.0% of respondents foresee "much better" financial performance next year, up from only 8.1% in 2023. Also, 26.6% expect "better" performance next year, up from 15.0% in 2023.

Positive Historical Biologic CDMO Outsourcing Trends…



… With Increasing Optimism for the Future



Source: BioPlan Associates (2024 Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production) and Bourne Partners

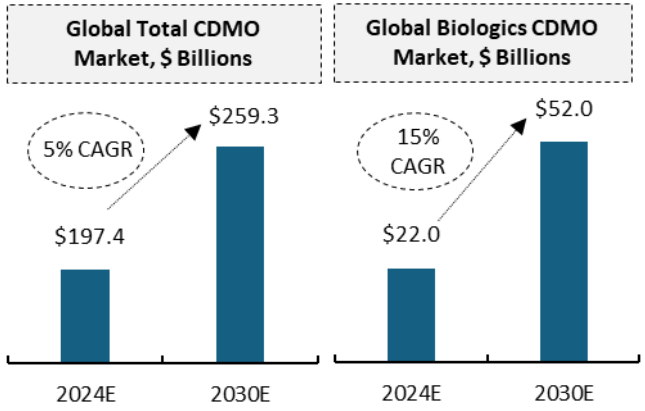
Three Example Opportunities within Precision Medicine

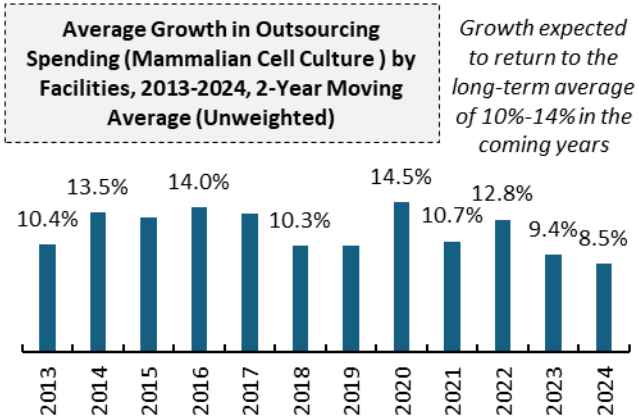
This focus on precision medicine is changing the structure of the CDMO landscape, in our view. We are monitoring a number of emerging verticals that require unique specialization and represent an opportunity for forward-looking CDMOs to embrace complexity and strategically position themselves as early market leaders (for outsized growth in the future).

1) Antibody-Drug Conjugates (ADCs). We see a significant opportunity for CDMOs in the ADC space. We estimate that total global sales of ADCs are $10+ billion. And, we expect this to increase to $40+ billion by 2030. A major limiting factor for growth will be the availability of manufacturing capacity. In our view, only a handful of CDMOs truly have end-to-end ADC manufacturing capabilities with the specialized facilities and equipment that is specifically needed for the manufacturing of ADCs.

2) Radiopharmaceutical Drugs. To date, much of the manufacturing of radiopharma drugs is being done in-house by the innovator. This is a market that is still nascent with total global sales of only a few billion dollars today. However, we think that this could double, triple, or even quadruple in the coming years with new radiopharma drugs coming to market -- as well as investments by pharma companies to address manufacturing bottlenecks.

3) Cell and Gene Therapy (CGT). We see a long-term opportunity for CDMOs in CGTs, despite a slower than expected uptake on these drugs due to high price points, sometimes in the multi-millions. Global spending on CGTs is expected to approach $25 billion in 2025. Many industry observers expect this to reach $60 billion by 2030 driven by the introduction of new CGTs coupled with increasing patient populations with cancer and rare diseases. This will put significant pressure on existing manufacturing capacity.





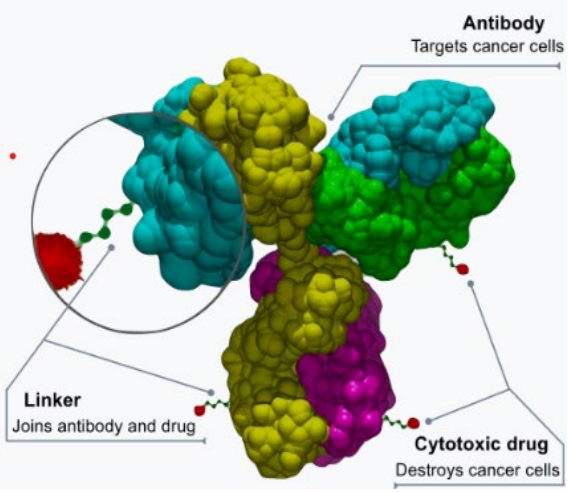
Source: Bioplan Associates and Bourne Partners

Overview of the Antibody-Drug Conjugate (ADC) Space

We see a significant opportunity for CDMOs in the ADC space. To date, fifteen ADCs have come to market (seven in the past five years) with two more approvals expected in 2025. Looking ahead, the need for ADC manufacturing is likely to surge with well over 150 ADCs in clinical trials, many of which involve unique antibody, cytotoxic, and linker technologies.

ADCs are a class of oncology drugs designed to deliver highly potent cytotoxic agents to a specific cancer cell -- while leaving the adjacent healthy cells alone. This contrasts with chemotherapy, which does not differentiate between cancer and healthy cells. For patients, this allows for the power of chemotherapy without the side effects (and dose limitations). Key commercially successful examples of ADC treatments are *Kadcyla* and *Enhertu* with 2023 sales of $2.6 billion and $2.2 billion, respectively.

Specifically, **the development of an ADC involves the selection of a target (tumour antigen)** -- i.e., a specific protein on the surface of a cancer cell. Then a monoclonal antibody is engineered to bind to this selected antigen. Attached to the antibody is a biologically active cytotoxic (chemotherapy) drug. Conjugation is next, during which the researcher develops a linker molecule to connect the cytotoxic drug to the antibody. These linker molecules allow the ADC to remain inactive while in the patient's circulation, only releasing the cytotoxic drug when the ADC is inside the targeted cancer cell.



Brand	Drug Name	Company	Approval Year	2023 Sales ($ Billions)
Enhertu	Trastuzumab deruxtecan	Daiichi Sankyo/AstraZeneca	2019	2.6
Kadcyla	Trastuzumab emtansine	Roche	2013	2.2
Adcetris	Brentuximab vedotin	Pfizer/Takeda	2011	1.7
Padcev	Enfortumab vedotin	Astellas/Pfizer	2019	1.1
Trodelvy	Sacituzumab govitecan	Gilead	2020	1.1
Polivy	Polatuzumab vedotin	Roche	2019	0.9
Elahere	Mirvetuximab soravtansine	ImmunoGen	2022	0.3
Besponsa	Inotuzumab ozogamicin	Pfizer	2017	0.2
Tivdak	Tisotumab vedotin	Genmab/Seagen	2021	0.1
Zynlonta	Loncastuximab tesirine	ADC Therapeutics	2021	0.1
Others				Not Material
Total				**$10.0+**

Source: Biopharma PEG, Foley & Lardner LLP, and Bourne Partners

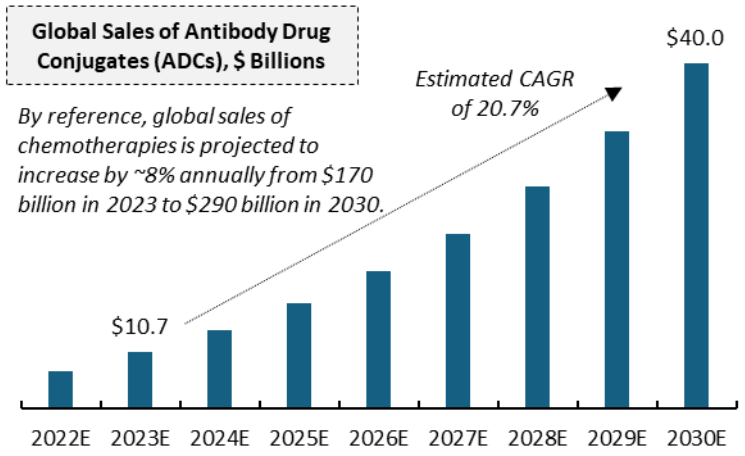
A Booming and Innovating Marketplace for ADCs

We expect demand for antibody drug conjugates (ADCs) to increase rapidly in the coming years fueled by the ongoing focus on precision medicines, the rising incidence of cancer, and new approvals in the current clinical trial pipeline. Today, we estimate that total global sales of ADCs are $10+ billion. This is expected to increase to $40+ billion by 2030.

ADCs are not a new concept, but recent innovations have turned ADCs into a rapidly growing therapeutic vertical. The first ADC was originally approved in 2000 to treat leukemia. However, the "ADC era" truly began in 2011. And, of the 15 ADCs approved to date, thirteen have been approved in the past ten years. Recent innovations include the use of less potent cytotoxic payloads to improve the safety profile of the drugs. Also, advances in linker and conjugation technologies have improved performance. Finally, conjugates are being explored outside of the cancer space in areas such as atherosclerosis and inflammatory diseases.

With rising optimism, **we have seen an upswing in acquisitions and partnership arrangements by Big Pharma.** The largest acquisition, by far, was the late 2023 acquisition of Seagan by Pfizer at a 30%+ premium to market. This was followed by Abbvie acquiring Immunogen at a 95% premium to market. Still, most of the dealmaking has come in the form of partnerships between larger pharma companies and smaller biopharma firms to carry out the initial stages of development, only taking over once the asset has been de-risked. The most notable partnering deal was between Merck and Daiichi Sankyo, which involved an upfront payment of $5.5 billion and a total deal value of $22 billion.

Date	Notable Deal Annnouncement	Type of Deal	Value $ Billions
Oct 2023	Merck / Daiichi Sankyo	Partnership	$22.0
Dec 2023	Pfizer / Seagan	Acquisition	43.0
Jan 2024	Roche / MediLink Therapeutics	Partnership	1.0
Feb 2024	AbbVie / Immunogen	Acquisition	10.0
Mar 2024	J&J /Ambrx Pharma	Acquisition	2.0
Mar 2024	Biotheus / Hansoh	Partnership	0.7
Apr 2024	Ipsen / Sutro Biopharma	Partnership	0.9
Apr 2024	Merck / Abceutics	Acquisition	0.2
May 2024	Genmeb / ProfoundBio	Acquisition	1.8



Source: Biospace, Company reports, and Bourne Partners

Is There Sufficient ADC Manufacturing Capacity?

Looking ahead, **a major limiting factor for the ADC marketplace will be the availability of manufacturing capacity.** Today, in our view, only a handful of CDMOs truly have end-to-end ADC manufacturing capabilities -- as well as the facilities and equipment specifically designed for the production and finishing of ADCs.

We estimate that the CDMO marketplace for ADCs is currently ~$2B annually -- and growing rapidly with 150+ potential new ADCs in clinical trials. However, this end market is fragmented across the manufacturing of the antibody, the cytotoxic payload, and the linker/conjugation technology -- as well as the fill–finish of the final product. As such, sponsors often need to juggle relationships with multiple CDMOs (production facilities) and individualized (and concurrent) manufacturing processes and supply chains.

Today, there are 80+ CDMOs promoting themselves as being able to manufacture ADCs. However, in our view, **only a fraction of these CDMOs have true end-to-end ADC production capabilities** as well as the facilities and equipment specific for the manufacturing of ADCs. Even fewer still have the regulatory expertise to ensure the production and testing are sufficient for successful approval.

Also, **biopharma companies developing ADCs need to be careful to ensure that a prospective CDMO is adequately funded** to invest in specialized facilities and/or equipment. As a result, we may see more sponsors/developers opting to build-out their own in-house ADC manufacturing capacity or to partner with larger pharma companies with the necessary “deep pockets.” Altogether, we think that the manufacturing planning process needs to start much earlier for ADCs than would normally be the case for other biopharma products.

Source: Abzena, Pharmasource, and Bourne Partners

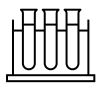
More on the Unique Challenges of ADC Manufacturing

In our view, **the manufacturing of ADCs includes unique complexities.** The fragmentation of the manufacturing process and the complexity of the supply chains raises the risk of product loss, contamination, and delayed market entry. Adding to this is the toxicity of the ADC materials themselves as well as the use of novel linker technologies in each ADC.

Unique Technologies. Many view the linker technology is the most difficult part of the ADC development and manufacturing process. The linker needs to be stable in a patient's bloodstream, but, at the same time, be able to fully release the cytotoxin "payload" at the target cell. Also, the linker needs to have no pharmacological action by itself (to avoid any additional toxicity to the patient). Finally, the site for conjugation needs to be very targeted such that every batch is the same with an optimal drug-to-antibody ratio to deliver a balance of toxic load. The precision of the linker is important to ensure that the right amount of cytotoxin is delivered to the cancer cell with no leftover adverse impact to neighboring cells.

Quality Control. Manufacturing quality control for ADCs requires coordinated analytics and testing to avoid impurities and ensure consistent/targeted drug-to-antibody ratios (DARs), i.e., the number of drug molecules conjugated to each antibody. A major challenge for manufacturers is that the conjugation process can lead to various mixes of antibodies and attached drug molecules, which, in turn, can lead to reduced efficacy and/or increased toxicity risk.

Safety and Handling. The cytotoxic payloads attached to the ADC are often hundreds/thousands of times more potent than a traditional chemotherapy drug. This significantly raises the importance of handling dangerous materials by workers, the use of dedicated storage, contamination prevention, cleaning and neutralization procedures, waste disposal, and facility design, e.g., back-up power generators, HVAC systems, temperature and environmental management, etc. This also necessitates the use of specialized equipment with materials that can neutralize the potent compounds and/or can be disposable. In our view, there are not many CDMOs with a track record for handling this type of material.



Fill Finish. The fill finish process for ADCs is the final stage of manufacturing during which the final product drug is aseptically filled into vials or other containers and prepped for packaging. This often is very complex involving lyophilization (freeze-drying) to ensure stability and potency of the product and specialized equipment given the cytotoxic nature of ADCs. In our view, the fill-finish process should ideally consist of dedicated facilities given the final filled product remains a risk with cytotoxic residuals on the exterior of the vial and the potential for contamination.

Source: Abzena, Pharmasource, and Bourne Partners

ADC CDMO Case Study: Abzena

One early leader in the ADC space that we are monitoring is Abzena. Abzena offers integrated development programs for various complex biologics and bioconjugates. In particular, Abzena's success with ADCs highlights the importance of involving a CDMO early in the development process to optimize product quality and accelerate time-to-market.

Key to Abzena's success in the ADC space has been its ability to support early-stage research -- essentially functioning as an extension of the sponsor's development teams. CDMOs need to be involved early in the development process to be responsive to unanticipated events that can occur with respect to the linker technology and the conjugation process. Abzena described itself to us as a "CRDMO" (with the "R" standing for "Research"). Today, Abzena employs 450 staff -- of which 75 have PhDs.

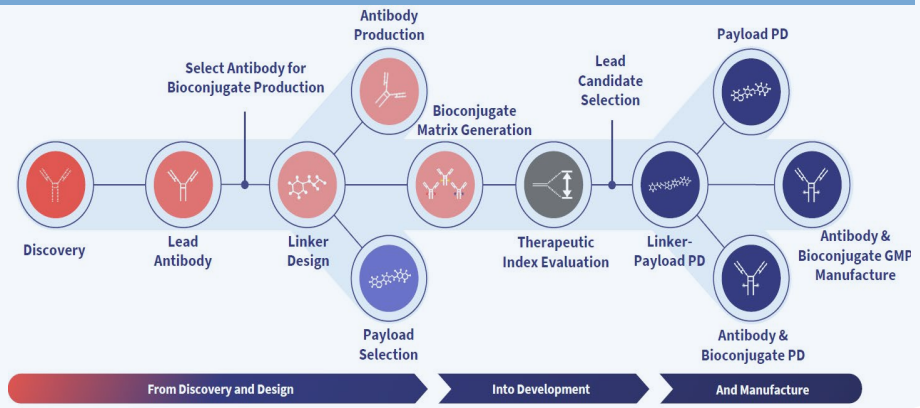
The complexity of ADC development and production makes sponsor-CDMO relationships very "sticky" as it is typically impractical for a sponsor to transition products between manufacturers. As such, being involved earlier in the development process positions Abzena to grow, over time, as its portfolio of prospective ADC drugs progresses through clinical trials and into full commercialization.

In addition to its capabilities in early-stage ADC research and development, **we view Abzena as differentiated by its ability to offer comprehensive services**. This helps sponsors avoid the logistical difficulties of juggling multiple outsourcing relationships.

Abzena Is Able to Provide Comprehensive Support for All Steps in the Design, Development and Manufacture of ADC Drugs

The selection of the optimal "linker" technology is key to the development of an ADC. Poor selection of a linker technology can result in inferior clinical efficacy, safety/toxicity risks, and delayed time-to-market.

Abzena offers proprietary linker technologies, e.g., its *ThioBridge* conjugation platform technology. However, management emphasizes the importance of being flexible with linker technologies, and Abzena never tries to force a specific "linker" technology on a sponsor.



Source: Abzena and Bourne Partners

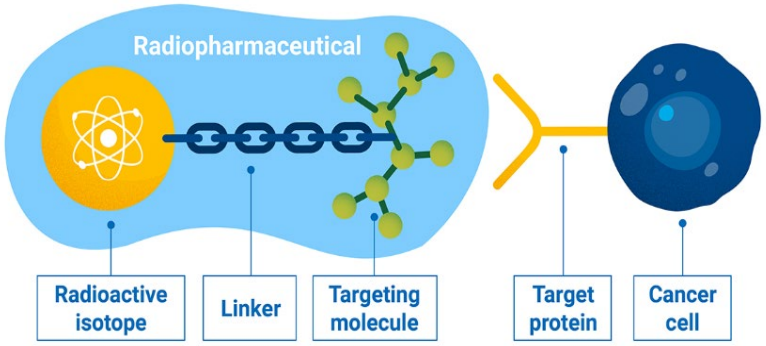
Overview of the Radiopharmaceutical Space

Another emerging vertical that we have been hearing more and more about is radiopharmaceuticals. To date, much of the manufacturing of radiopharma drugs is being done in-house by the sponsor/innovator. However, over time, as the application of these drugs expands, we see a potentially sizeable opportunity for specialized CDMOs in this area.

Radiopharma drugs are a form of precision medicine that utilizes the power of radiation to target and treat diseased cells, typically cancerous cells. Unlike chemotherapies and antibody therapies, radiopharmaceuticals do not rely on chemical interactions. Instead, these drugs attach to cancerous cells and deliver radiation to kill the cells regardless of the chemical signaling involved. Importantly, the impact to adjacent healthy cells is minimized, avoiding many of the negative side effects of chemotherapy, surgery, external beam radiation, and/or hormonal therapy. Also, if these drugs do not find their target, they are designed to exit the body safely and swiftly.

A typical radiopharmaceutical consists of three components. First is a ligand, which is a peptide, small molecule, or antibody that is capable of binding to a specific biomarker or receptor of a target (cancer) cell. Second is a radioactive isotope, which emits high-energy particles that kill the diseased cell by damaging its DNA. Third is a linker (or a chelating agent or chemical bonding site) that is able to connect a radioactive isotope to a ligand until the drug reaches and binds to the target cell.

Outside of treating diseases, **radiopharmaceuticals are used for diagnostic purposes** with the radioactive isotope emitting positrons or gamma rays that can be picked up by imaging technologies such as PET (positron emission tomography) or SPECT (single-photon emission computed tomography). This allows physicians to visualize the location and size of tumors within a patient's body.



Example Radiopharmaceutical CDMOs

ALMAC, Nucleus RadioPharma, Siemens Healthineers, SOFIE From start to clinic, RPH, NorthStar Medical Radioisotopes, LLC, Eckert & Ziegler, CardinalHealth, agilera, MRP Medi-Radiopharma, AtomVie Global Radiopharma, RadioMedix Innovating Theranostics, GMS, minerva IMAGING, IONETIX, nihon medi+physics, SpectronRx, EVERGREEN THERAGNOSTICS, itm, PharmaLogic Take The Lead

Source: Pharmasource and Bourne Partners

Rapidly Evolving Radiopharmaceutical Marketplace

The marketplace for radiopharmaceuticals is still nascent and rapidly evolving with an end-market opportunity of a few billion dollars today. However, we think this end-market could double, triple, or even quadruple in the coming years with new drugs coming to market -- as well as investments by large pharma companies to address manufacturing bottlenecks.

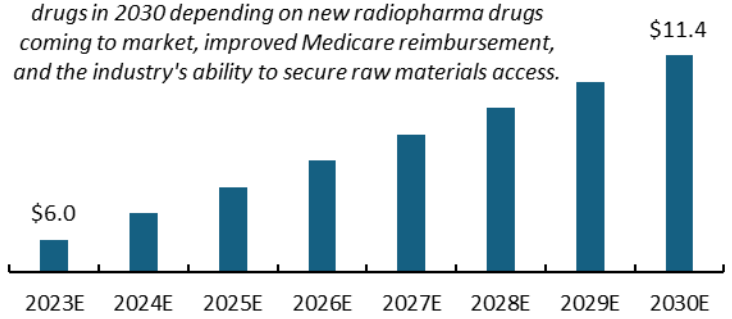
The use of radiation to treat diseases dates back a century with the use of radioactive iodine for thyroid conditions and cancer.

However, interest and media attention on radiopharma has particularly exploded in recent years as a result of the commercial success seen by Novartis with Latathera (for a certain pancreatic cancer; approved in 2018) and Pluvicto (for prostate cancer; approved in 2022). Combined, these two drugs are broadly projected to generate about $4 billion of annual sales within a few years as new production capacity comes online. A primary challenge for Novartis has been its ability to access sufficient isotope raw material to meet patient demand. This has resulted in Novartis investing upwards of $300 million to open and expand several radiopharma manufacturing sites.

Following Novartis's success, **we have seen a series of sizable acquisitions/investments by large pharma companies in the radiopharma space**. In many of these cases, the acquired companies were explicitly selected based on their inhouse capacity to produce sufficient quantities of their own product given strong demand, a lack of specialized CDMO providers, and the raw material challenges experienced by Novartis.

Global Sales of Radiopharmaceuticals, $ Billions

We see significant upside to the market for radiopharma drugs in 2030 depending on new radiopharma drugs coming to market, improved Medicare reimbursement, and the industry's ability to secure raw materials access.



Date	Select Deal Announcements	Type of Deal	$ Billions
Oct 2017	Novartis / Advanced Accelerator	Acquisition	$3.9
Oct 2018	Novartis / Endocyte	Acquisition	2.1
Dec 2023	Eli Lilly / Point BioPharma	Acquisition	1.4
Feb 2024	Bristol Myers Squibb / RayzeBio	Acquisition	4.1
Apr 2024	AstraZenica / Fusion Pharma	Acquisition	2.4
Apr 2024	Novartis / PeptiDream	Licensing	2.7
May 2024	Eli Lilly / Atkis Oncology	Partnership	1.1
May 2024	Novartis / Mariana Oncology	Acquisition	1.0
Jul 2024	Eli Lilly / Radionetics	Licensing	0.1
Sep 2024	Sanofi / RadioMedix/Orano Med	Licensing	0.4
Oct 2024	Telix Pharma / Rhine Pharma	Spin-Off	n/a
Nov 2024	Novartis / Ratio Therapeutics	Licensing	0.7

Source: Precedence Research, Company reports and Bourne Partners

Reasons for Optimism for the Future of Radiopharma

Our optimism for the radiopharmaceutical space, despite its relatively small size, is based on potential significant upside to current marketplace assumptions based on new therapies (and diagnostics) coming to market and the impact of improved Medicare reimbursement for diagnostic applications.

New Radiopharmaceutical Therapies Coming to Market

Looking ahead, **there are multiple dozens of clinical trials involving radiopharmaceuticals.** To date, radiopharma drugs have generally been reserved for patients who have exhausted other treatment options. However, over the years, the effectiveness and low toxicity of these drugs have resulted in researchers evaluating their use earlier in the treatment process and in combination with other therapies, e.g., immunotherapies, chemotherapies, and hormonal therapies. As an example, there is optimism around several clinical trials by Novartis to integrate Pluvicto (for prostate cancer) into earlier lines of therapy, which could multiply sales of this drug. Also, there are, at least, twenty other cancers being targeted, e.g., breast, pancreatic, small cell lung, etc., many of which include extensions of existing therapies (which have already been proven to be safe for humans).

Other sponsors are investing in new/next-generation targeting molecules and new forms of radiation. A number of novel targeting molecules have emerged such as DARPins, aptamers, small/high-affinity peptides, and cyclic DNA/RNA. These targeting molecules have higher binding affinities and faster clearance from the body. Separately, the use of alpha particles is being researched (by companies like RayzeBio) as a way to deliver more damage to resistant cancer cells that have survived other treatments.

Improved Medicare Reimbursement for Radiopharmaceutical Diagnostics

Recent regulations should improve Medicare reimbursement for radiopharmaceutical diagnostic scans. In January 2025, the Centers for Medicare & Medicaid Services (CMS) started to pay a separate Medicare rate for the use of diagnostic radiopharmaceuticals with per-day costs exceeding $630. This is a significant improvement from the previous reimbursement methodology, which bundled diagnostic radiopharma drugs as “supplies.” This should encourage investment in radiopharma imaging equipment and agents, particularly by smaller community hospitals and healthcare providers with limited budgets. Separate payments will now be based on mean unit cost (MUC) derived from hospital claims data.

Source: Bourne Partners

Quality Control in Radiopharmaceutical Manufacturing

There are unique considerations to the manufacturing (and distribution) of radiopharma drugs that distinguish them from traditional drugs. For these reasons, biopharma sponsors, even large pharma companies, often look to partner with third-party CDMOs specialists. CDMOs must have the operating procedures, supplier relationships, production and analytical equipment to install, qualify, and validate, in a timely manner, the production and testing of radiotherapies.

In our view, **the top challenge of radiopharmaceutical manufacturing is the need for heightened quality controls due to the handling of radioactive materials.** Because of this, diagnostic and therapeutic radiopharma products must comply with the FDA's cGMP regulations (21 CFR 210 and 211 for therapeutics and 21 CFR Part 212 for PET diagnostic agents). On top of this, the Nuclear Regulatory Commission (NRC) imposes guidelines related to the handling, transportation, chain-of-custody, and administration of radioactive materials. Errors in the production of therapeutic radiopharma drugs can cause significant harm to patients.

- ***Administration.*** Most radiopharma drugs are administered intravenously. Because of this fact, they must be manufactured in highly controlled environments (e.g., ISO Class 5 areas per ISO 14644 standards) with continuous production monitoring and different approaches to packaging, testing, and shipping.
- ***Sterility.*** Assuring product sterility is a challenge since many radiopharma products need to be shipped so quickly -- often prior to any sterility results being available. This necessitates the use of rapid bacterial endotoxin testing and microbial detection to provide visibility into any contamination while maintaining CGMP compliance. Endotoxins, in particular, are a major risk, but traditional endotoxin testing methods, such as the Limulus Lysate (LAL) testing, take too much time for radiopharma drugs.
- ***Impurities.*** Radiochemical Impurities can emerge during production, impacting the therapeutic effectiveness of the drug (or leading to unexpected side effects). High-performance liquid chromatography (HPLC) and thin-layer chromatography (TLC) are analytical techniques often used to assess radiochemical purity.
- ***Raw Material Supply.*** The isotopes used in the manufacturing radiopharma drugs can vary in quality and supply so there needs to be strict monitoring of suppliers, including qualification processes, audits, and testing of inbound raw materials. Backup supply sources are essential for mitigating the risk of disruptions, especially given the unpredictable nature of isotope supply chains.

Source: Bourne Partners

More on Radiopharmaceutical Manufacturing Challenges

On top of the need for heightened quality control, **the manufacturing of radiopharmaceuticals has a number of other unique challenges such as accelerated timelines, inventory management, and complex supply chain logistics.** Also, the radiopharma CDMO market is underdeveloped so many biopharma sponsors must build production capacity in-house.

Accelerated Timelines. Radiopharma drugs (and their raw materials) have only a few days of shelf life due to the physics of radioactive decay. Sponsors and CDMOs should have relationships with multiple isotope suppliers. At the same time, clinicians must also be able to quickly prepare and administer these drugs otherwise the radiopharmaceutical product may decay before it reaches the patient. Altogether, this requires the coordination of manufacturing, regulatory compliance, and clinical administration.

Supply Chain Flexibility. Radiopharma drugs must often be shipped vast distances -- domestically and internationally. Without tracking and redirection capabilities, simple weather-related events, such as a thunderstorm, can delay shipments, leading to waste, increased costs, and harm to patients. In many cases, pharma companies rely on ground transportation from the factory to the clinician to minimize the risk of weather-related disruptions. This often requires a regional distribution model with real-time tracking.

Ability to Scale. A CDMO must have the scalability to flex production up and down as needed to avoid wasted doses. For instance, a CDMO might need to double its production before and after seasonal holiday periods to meet patient demand. This relates to physical equipment, facilities, and staff. Radiopharma companies run the risk of being unable to reserve the needed capacity to deliver clinical trials and commercial launches.

Distribution Channel. Critical for the growth in the radiopharma space will be expanding the use of radiopharma drugs at community hospitals (where 80% of cancer patients are treated). Clinical/medical providers need to upgrade their medical licenses to be allowed to handle radioactive material before administering radiopharma drugs. As a result, the majority of radiopharma therapies are still delivered at only a handful of academic and/or specialized medical centers due to the logistical challenges associated with the handling of radioactive materials, the implementing safety protocols, and the need for specialized equipment.

Information Technology. Many manufacturers are evaluating artificial intelligence (AI) and machine learning to help analyze large quantities of data in real time to predict issues before they arise.

Source: Bourne Partners

Radiopharma CDMO Case Study: PharmaLogic

One early leader in the radiopharma space we are monitoring is PharmaLogic. Most of PharmaLogic's revenues are generated from its radiopharmacy business. However, we see PharmaLogic as well positioned for significant growth at its radiopharma CDMO business given its ability to work with radioactive materials and its expansive distribution network.

Founded in 1993, **PharmaLogic originated in the radiopharmacy space with the company recently morphing into a radiopharma CDMO.** Today, the vast majority of PharmaLogic's revenues are generated from the manufacturing and distribution of injectable radiopharma diagnostics, including diagnostics designed to emit gamma-emitting radioisotopes detectable by SPECT (single-photon emission computerized tomography) and diagnostics designed to emit positrons detectable by PET (positron emission tomography). PharmaLogic has been owned by Webster Equity Partners and MedEquity Capital since March 2025.

As the radiopharma market evolves, **we see PharmaLogic as well positioned to be an early leader in the radiopharma CDMO space** with a demonstrated ability to handle radioactive materials and with a distribution network of 50+ sites (and increasing) across North America and Europe. This geographic coverage is critical for sponsors given the variable and short half-life of many radiopharma drugs in development. A CDMO needs to be located within a few hours of a hospital in order to be able to produce and deliver radiopharma drugs to patients in a timely manner. Also, this network includes a number of 21 CFR 211 facilities designed to produce and handle radioactive materials and a dozen or so sites designed to host clinical trials.

The year 2024 was a busy period for PharmaLogic with multiple capacity expansions to support growth, including the opening of new radiopharma production and research facilities in Cincinnati, Ohio (April 2024), Bronx, New York (May 2024), Salt Lake City, Utah (October 2024), and Los Angeles California (October 2024).

Source: PharmaLogic and Bourne Partners

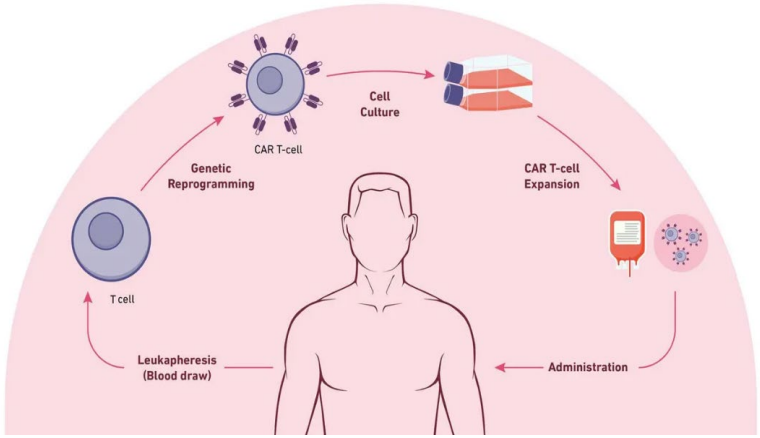
Overview of the Cell and Gene-Based Therapy Space

We see a significant opportunity for CDMOs in cell and gene therapies (CGTs), despite a temporary overbuilding of capacity in recent years. With hundreds of CGTs in clinical trials, we expect an improving supply/demand dynamic for CDMOs as new products need to achieve commercial scale and as the industry works through reimbursement challenges.

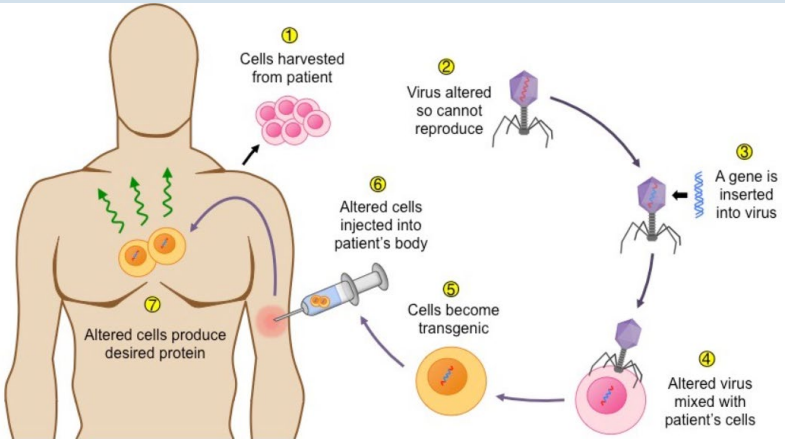
CGTs are a form of precision medicine that uses genetic material. Cell therapy involves reintroducing entire cells into a patient's body to treat a disease or give rise to new, healthy cells. There are many variations of cell therapies. Autologous cell-based gene therapy involves the removing of cells from a patient, altering them in a laboratory, and re-implanting them back into the patient's body. Using the patient's own cells makes it less likely to cause negative immune responses, although the treatment would only be applicable to that patient. Allogeneic cell therapy uses cells from healthy donors and can be applied to a broader population of patients.

A gene therapy similarly involves replacing a diseased or damaged gene with a modified copy of that gene to inactivate or treat a disease. There are many variations of this approach. Often, this is done with a viral vector (e.g., an adenovirus) being delivered via a therapeutic gene to a targeted cell. To date, the U.S. Food and Drug Administration (FDA) has approved a variety of gene therapies for cancer, chronic conditions, and rare diseases. However, for most patients, gene therapies are only accessible through clinical trials.

Example Application of Cell Therapy



Example Application of Gene Therapy



Source: Bourne Partners

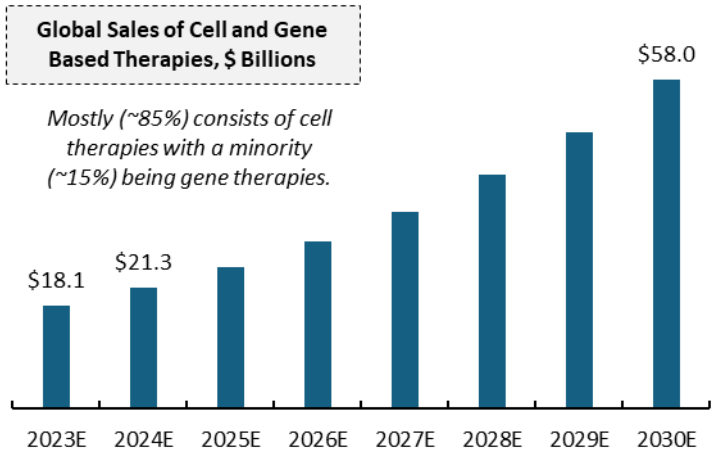
Marketplace for Cell and Gene-Based Therapies

We estimate that global spending on cell and gene therapies (CGTs) will approach $25 billion in 2025 with nearly 20% annual growth thereafter -- driven by new regulatory approvals and increasing patient populations with cancers and rare diseases. Many industry observers expect a global marketplace for CGTs of almost $60 billion by 2030.

To date, **the U.S. Food and Drug Administration (FDA) has approved 43 CGTs.** This includes two legitimate "blockbuster" CGTs -- Yescarta ($1.5 billion in annual sales) and Zolgensma ($1.2 billion in annual sales). There are 400+ prospective CGTs in clinical trials so the number of approved CGTs will likely grow rapidly in the coming years. The COVID-19 pandemic slowed down clinical trials; however, this has since recovered. Also, 2024 was a breakthrough year for CGTs, with the first FDA-approved engineered cell therapy for solid tumors and the first FDA approval for a gene therapy directly administered to the brain.

The high price of these treatments continues to be the primary barrier to adoption (and coverage). The average price of a CGT per patient ranges widely from $500k to as high as $4 million per treatment. These high price points require collaboration between biopharma sponsors, healthcare providers, and health plans to ensure patient access to these therapeutics. In our view, the rise of value-based payment models could be helpful for CGTs to achieve commercial success.

Brand	Company	Approval Year	2023 Sales ($ Billions)
Yescarta	Kite, a Gilead Company	2017	1.5
Zolgensma	Novartis	2019	1.2
Kymriah	Novartis	2017	0.5
Carvykti	Janssen Biotech and Legend Biotech	2022	0.5
Abecma	Bristol Myers Squibb and 2seventy bio	2021	0.5
Tecartus	Kite, a Gilead Company	2020	0.4
Breyanzi	Bristol Myers Squibb	2021	0.4
Elevidys	Sarepta Therapeutics	2023	0.2
MACI	Vericel	2016	0.2
Luxturna	Spark Therapeutics (Roche)	2017	0.1
Others			Not Material
Total			**$18.1**



Source: Precedence Research and Bourne Partners

An Emerging Cell/Gene Therapy CDMO Marketplace

The global cell and gene therapy (CGT) CDMO marketplace is estimated to be $5B-$8B annually with projections to reach $30B-$35B by 2030 -- implying 20%+ annual growth. Yet, the CDMO landscape is highly fragmented with only a handful of full-service CGT CDMOs with a complete suite of services from preclinical to commercial-scale manufacturing.

One of the major challenges to CGT production is high development and manufacturing costs, particularly in an environment of scarce capital. As such, well-resourced pharma companies are well positioned to commercialize CGTs that they develop themselves or in partnership with small biopharma sponsors. A decade ago, the belief among cell and gene therapy developers was that Big Pharma was never going to "get their heads around" this nascent market. Now, large pharma companies are shaping the space. According to the Alliance for Regenerative Medicine (ARM), there has been uptick in investment in cell and gene therapies in 2024, with 13 of the 15 largest pharma companies having an "active presence" in the space.

Small/mid-sized biopharma firms can also outsource to a specialist CGT CDMO to access specialized expertise, state-of-the-art facilities, technologies, and equipment that would be generally unavailable internally. This results in greater efficiency and speed as well as lower costs. Selecting the right CGT CDMO partner can be difficult, requiring significant due diligence, protections of intellectual property, and significant oversight of quality controls and data integrity. Also, regulatory requirements for CGTs are rapidly evolving and regulatory agencies are increasingly scrutinizing manufacturing processes to ensure safety and efficacy.

There is a broad expectation of consolidation in the CGT CDMO space in the coming years led by the major global CDMOs such as Catalent, Lonza, Samsung Biologics, Thermo Fisher Scientific, and WuXi AppTec. Today, most CGT CDMOs vary based on service scope and expertise. Niche CGT CDMOs specialize in specific areas such as viral vector production, cell line engineering, or fill-finish operations. Other emerging CGT CDMOs offer innovative technologies, often focusing on specific cell or gene therapy modalities.

Source: Pharmasource and Bourne Partners

Manufacturing Challenges for Cell/Gene Therapies

There are a number of challenges in the manufacturing of cell and gene-based therapies (CGTs) -- all of which generally stem from the complexity and heterogeneity of these therapies. Adding to this, there is a choice of vectors (such as viral vectors), cell types (stem cells, T cells, etc.), and gene-editing techniques (CRISPR, TALENs, etc.). Three of the common challenges that we hear about across the CDMOs we have engaged with are scalability, quality controls, and staffing.

1) Scaling. In our view, the ability to scale-up (and down) CGT manufacturing is a primary reason why a number of CGT innovators have struggled in recent years. CDMOs must have flexible manufacturing to adapt to varying production scales and accommodate the unique requirements of different therapies, from autologous to allogeneic approaches. However, regulatory bodies, such as the FDA, often require biopharma sponsors to document their manufacturing processes to get approval. This makes it difficult to adapt manufacturing processes when there is a need to scale up production (or when circumstances change). As such, manufacturing plans need to be considered early in the development process to determine viability of a therapy. Also, many biopharma firms are focused on locating manufacturing sites closer to hospitals. (Point of care commercial manufacturing is a topic also being talked about.)

2) Quality Controls. Quality control is particularly difficult in the CGT space given the significant amount of manual work that goes into CGT manufacturing. This necessitates frequent inspections and testing as well as the use of information technology, artificial intelligence and machine learning to detect product defects as soon as possible. Also, many CGTs have short shelf-lives, complicating handling and storing to ensure product quality. Finally, raw material variability, e.g., viral vectors, plasmids, and cell culture media, can have negative effects on the long-term safety and effectiveness of the end product. Manufacturers must have strong relationships with suppliers, and more manufacturers are adopting software to give them real-time visibility into their supply chains.

3) Workforce. Another challenge in CGT manufacturing that we continue to hear about is labor shortages. The challenge here is that much of the production of CGTs involves highly technical staff. A recent study by the Alliance for Regenerative Medicine highlighted labor shortages across manufacturing, analytical development and testing positions, as well as in quality control. The university system has been unable to keep pace with the rapid development in research in CGTs. To address this, CGT manufacturers need to develop and offer training programs to help their staff keep up with changing technologies and regulations. Also, over time, CGT manufacturers can find ways to automate manufacturing processes to reduce the need for human labor.

Source: The Alliance for Regenerative Medicine and Bourne Partners

Reimbursement Challenges

Key to the financial success of cell and gene therapies (CGTs) is the adoption and use of value-based reimbursement, in our view. The current fee-for-service reimbursement environment creates an untenable situation of having to ask health plans to pay a high price today for an uncertain value in the future. This is particularly a structural issue for commercial (employer-based) health plans since coverage regularly changes as members shift employers.

A major barrier to the success of CGTs is their ability to gain commercial traction with payers given their eye-wateringly high price points, sometimes in the multi-millions. This is a growing problem for the healthcare system with hundreds more CGTs now in clinical trials. As one simple example, almost two-thirds of the 100,000 Americans with sickle cell disease are funded by Medicaid. To treat these eligible SCD patients with a $2 million gene therapy implies $120 billion of incremental spending. Also, for CGTs introduced in recent years, there is limited long-term data on safety and sustainability of their effects.

In our view, **the ultimate success of the CGT space is linked to the ability of CGT sponsors and health plans to set up and execute value-based reimbursement models.** Value based reimbursement allows for payments to the sponsor over time based on the durability of the effect (and safety) of a CGT vis-à-vis pre-agreed upon performance metrics. To date, commercial payers are considering a variety of reimbursement options, including rebates or milestone-based payments based on the achievement and documentation of certain outcome metrics. Other ideas being considered include amortization payments to CGT sponsors over time, the formation of multi-payer risk-sharing pools, payer/manufacturer risk-sharing, and cost-caps. State governments are also using CGT carve-outs or reinsurance programs to help protect Managed Medicaid plans from financial hardships.

A potential important catalyst for the use of value-based reimbursement models for CGTs is the federal government's new "Cell and Gene Therapy Access Model." Now going into effect, the CGT Access Model is a voluntary alternative payment model that initially focuses on the use of two pricey CGTs for sickle cell disease in Medicaid. Essentially, the Centers of Medicare and Medicaid Services (CMS) would negotiate and oversee multi-state value-based reimbursement contracts with CGT manufacturers on behalf of state Medicaid programs. Over time, the hope is that the CGT Access Model can be expanded into other diseases and provide a framework for commercial health plans to pursue similar approaches. Of note, President Trump issued an executive order on January 20, 2025 to close down this program; however, media reports are suggesting that this program is still proceeding as planned.

Source: Bourne Partners

Profiles of Selected Cell and Gene Therapy CDMOs (1 of 2)

Cellipont Bioservices

The Woodlands, Texas

www.cellipont.com

Cellipont Bioservices (previously known as Performance Cell Manufacturing) was established in 2019 for the development and manufacturing (small/large batch) of cell-based therapies. In particular, Cellipont Bioservices has announced a number of recent business wins in areas such as master cell banking, CAR-T manufacturing, and fill finish processing, among others

To support demand growth, in March 2024, Cellipont Bioservices announced the grand opening of its purpose-built 76,000 square foot cell therapy manufacturing facility in The Woodlands, Texas with seven clean rooms, quality control labs, temperature-controlled storage, and segregated shipping bays. Also, this facility will host a "Cryopreservation Excellence Center" in partnership with *Evia Bio* (Minneapolis, Minnesota), a developer of "cold chain" solutions for cell therapies.

In 2021, Great Point Partners, a private equity investor, acquired a majority equity stake in Cellipont Bioservices with an additional capital infusion from HealthQuest Capital in late 2024 to fund new growth initiatives in 2025 and 2026.

Genezen Laboratories

Indianapolis, Indiana

www.genezen.com

Founded in 2014, Genezen Laboratories is a gene and cell therapy CDMO focused on early-phase process development, vector production, and analytical testing services. Through 2020, Genezen benefited from partnerships with Cincinnati Children's Hospital and Indiana University, leading to the company being acquired by Ampersand Capital Partners in 2021. Ampersand funded the construction of a 25,000 square foot cGMP-compliant lentiviral vector production facility outside of Indianapolis in Fisher, Indiana to support preclinical and clinical projects.

Today, Genezen Laboratories continues to be owned by Ampersand Capital Partners. In late 2023, Ampersand Capital Partners announced an $18.5 million follow-on investment to accelerate capacity expansions.

Notably, in July 2024, Genezen acquired the commercial gene therapy operations of uniQure (Nasdaq: QURE) in Lexington, Massachusetts and took over supply agreements for uniQure's clinical portfolio and the commercial production of a gene therapy of CSL Behring (ASX:CSL).

Source: Company reports and Bourne Partners

Profiles of Selected Cell and Gene Therapy CDMOs (2 of 2)

Minaris Regenerative Medicine

Allandale, New Jersey

www.rm.minaris.com

Founded in 1999, Minaris Regenerative Medicine (previously Progenitor Cell Therapy) is a cell and gene therapy CDMO offering autologous and allogeneic manufacturing services out of six facilities in the United States, Germany, and Japan. Specifically, Minaris offers product characterization, process, assay, analytical method and development, quality control and assurance, and clinical manufacturing, among other services.

In our view, Minaris Regenerative Medicine is best known for its role in manufacturing pivotal study batches for Dendreon's Provenge over a decade ago -- the first cell therapy approved for cancer treatment. More recently, in May 2024, Minaris began the commercial manufacturing of LYFGENIA (by bluebird bio) in the United States for sickle cell disease. Today, Minaris has a track record for commercial cell and gene therapy manufacturing in Japan, Europe, and the United States.

Minaris was a subsidiary of Resonac Holdings Corporation (a Japanese chemical company) until it was sold to the private equity investment firm Altaris in January 2025.

RoslinCT

Edinburgh, United Kingdom

www.roslinct.com

RoslinCT is a CDMO supporting sponsors of cell-based therapeutic products. The company was originally founded in 2006 as a spin-out from the Roslin Institute, a thought leader in the field of genetic and cellular biology. Today, RoslinCT operates five sites in the United Kingdom and one in Boston (the United States) on behalf of a broad base of biopharma customers.

In January 2022, GHO Capital Partners acquired RoslinCT to fund capacity expansions, product diversification, and acquisitions. Soon thereafter, in June 2023, RoslinCT acquired Lykan Bioscience, giving the company a presence in North America.

We believe RoslinCT is best known as one of the first in the world to manufacture clinical-grade human pluripotent stem cells (i.e., Dolly the Sheep). Also, in support of Vertex Pharmaceuticals, RoslinCT developed and commercialized the first CRISPR-edited cell therapy, CASGEVY (exagamglogene autotemcel), for sickle cell disease and transfusion-dependent beta-thalassemia. RoslinCT is currently manufacturing CASGEVY out of its Boston facility and several of its facilities in the United Kingdom.

Source: Company reports and Bourne Partners

Valuation Considerations

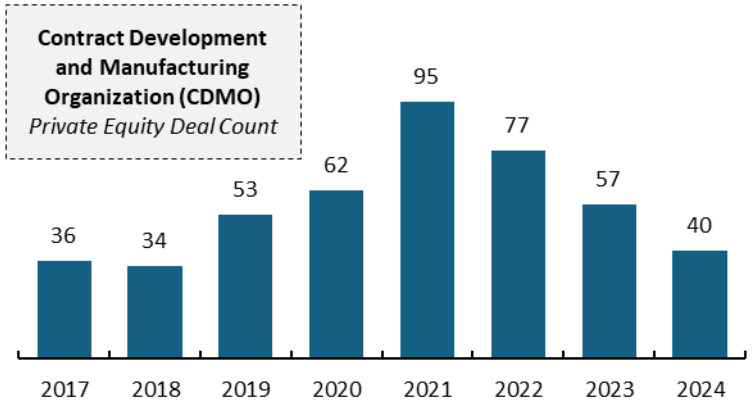
Expecting More Pharma Services and CDMO Deal Activity

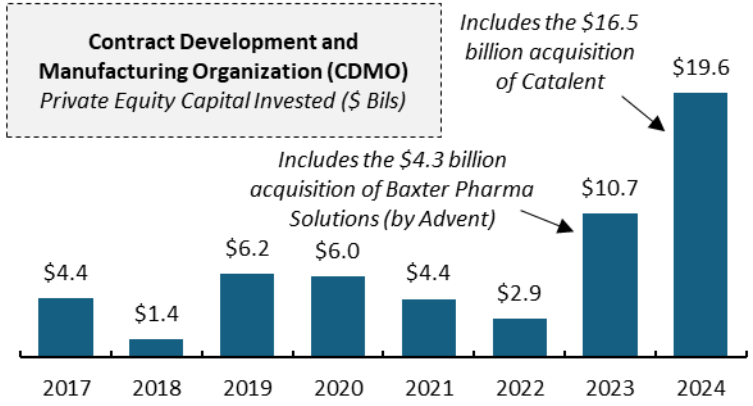
Pharma services private equity deal activity softened in 2023 and 2024, and this was certainly the case for CDMOs. We attribute this mainly to the effect of higher interest rates on the ability of acquirors to access debt financing. Also, CDMOs faced a volatile demand environment, particularly related to COVID-19 related products.

Looking ahead, **we see the fragmentation of the CDMO space as particularly interesting for private equity investors** given the opportunity to create economies of scale – i.e., acquiring a group of small CDMOs, integrating them, and selling them, as a platform, with premium EBITDA multiples. Also, we see opportunities for private equity driven consolidation around high growth CDMOs focused on complex precision medicines, which require specialized expertise, services, and manufacturing infrastructure.

Adding to this, **the Trump administration appears relentlessly focused on rebuilding domestic pharma manufacturing** -- as a matter of national security. Potentially new and ongoing tariffs on Canada, China, and Mexico is already causing large pharma companies to announce plans to shift production infrastructure back to the United States, and we are hearing more and more interest in shifting business towards domestic CDMO.

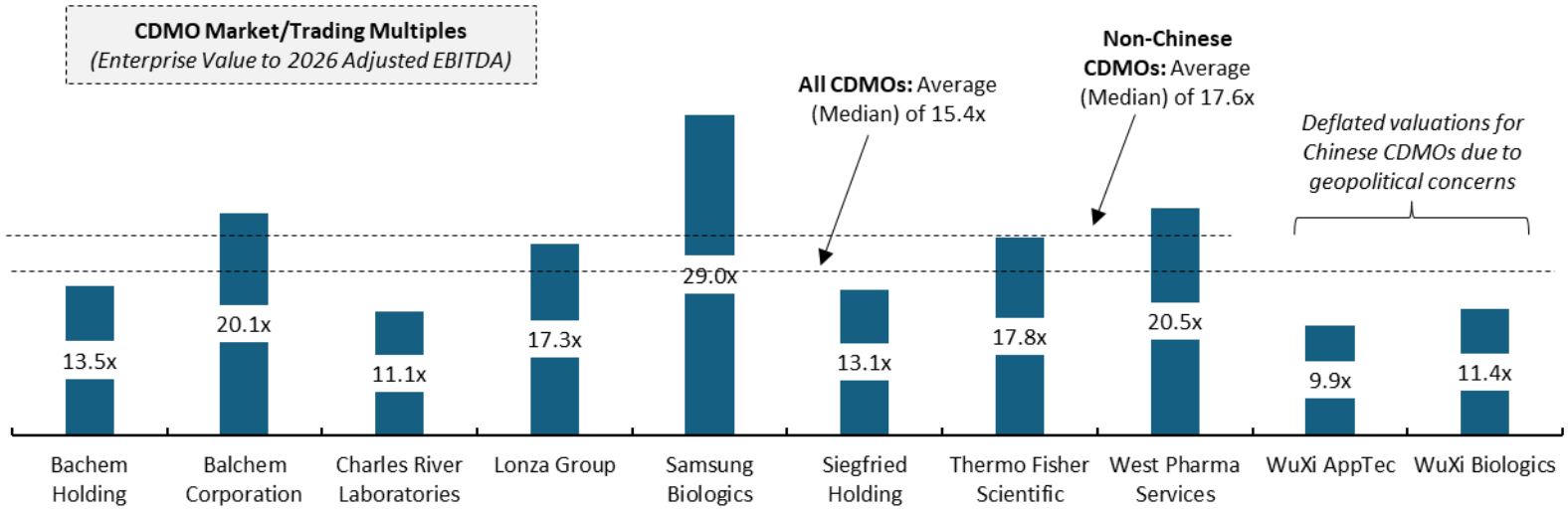
In our view, **recent large CDMO transactions in recent months could be the front-end of a return** to more merger and acquisition activity in 2025 and 2026, in our opinion. Notably, this includes the mega-acquisition of *Catalent* by *Novo Holdings* (for $16.5 billion) -- as well as *Avid Bioservices* being acquired by *Ampersand*, and *PCI Pharma Services* being acquired by *Blue Owl*, among others.





Source: Pitchbook and Bourne Partners

Current Public CDMO Valuation and Trading Comparisons



Company Name	Enterprise Value	Projected CY2026 Revenue	Growth	Multiple	Projected CY2026 EBITDA	Growth	Multiple	Debt Ratio
Bachem Holding	$4,470	$1,088	37.7%	4.1x	$331	46.8%	13.5x	-0.3x
Balchem Corporation	5,472	1,081	7.1%	5.1x	273	4.1%	20.1x	0.6x
Charles River Laboratories	10,838	4,030	5.4%	2.7x	974	6.5%	11.1x	2.7x
Lonza Group	50,054	9,773	11.8%	5.1x	2,895	15.7%	17.3x	1.1x
Samsung Biologics	52,342	4,323	15.5%	12.1x	1,808	18.9%	29.0x	0.1x
Siegfried Holding	5,119	1,687	8.6%	3.0x	391	11.1%	13.1x	1.3x
Thermo Fisher Scientific	221,303	46,832	6.8%	4.7x	12,409	9.0%	17.8x	2.2x
West Pharma Services	16,144	3,088	6.8%	5.2x	789	12.1%	20.5x	-0.2x
WuXi AppTec	24,876	6,687	12.7%	3.7x	2,509	13.3%	9.9x	-0.6x
WuXi Biologics	12,860	3,206	14.2%	4.0x	1,130	15.5%	11.4x	-0.7x
Average (Mean)			**12.7%**	**5.0x**		**15.3%**	**16.4x**	**0.6x**
Average (Median)			**10.2%**	**4.4x**		**12.7%**	**15.4x**	**0.3x**

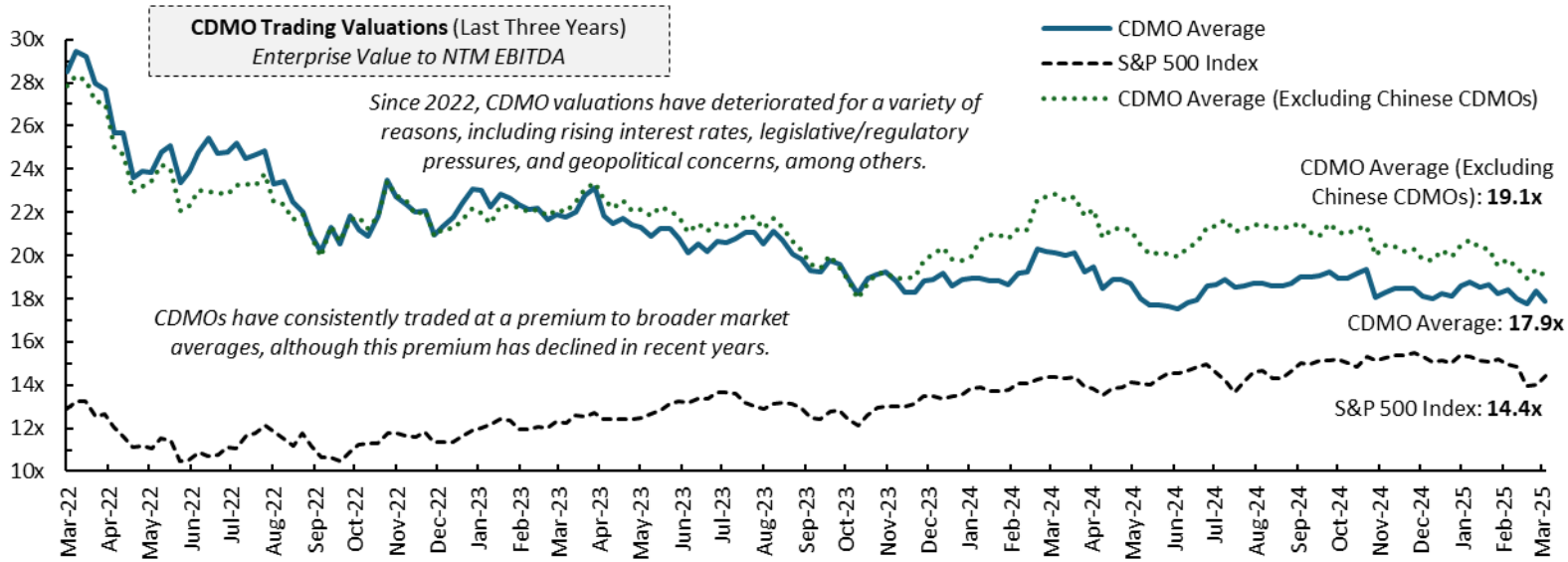
Note: Market values as of the close of business March 25, 2025.
Source: S&P Global Intelligence and Bourne Partners

CDMOs Have Consistently Traded at Premium Levels

Valuations on publicly-traded CDMOs remain at a healthy premium to the broader equity market. Today, on average, CDMOs are trading at 17.9x NTM EBITDA -- *a full 24% premium* to the S&P 500 Index. And, excluding the Chinese CDMOs (Wuxi Apptec and Wuxi Biologics), CDMOs are trading at 19.1x NTM EBITDA -- *or a 32% premium* to the S&P 500 Index.

In our view, **the simple explanation of the premium valuation for CDMOs is their consistently higher revenue growth.** This growth, in turn, is being driven by highly visible secular trends -- including an aging population globally and an increasing prevalence of diseases -- coupled with advances in science that are allowing for the development of more effective, targeted, and safe drugs.

Granted, **the CDMO premium (vs the S&P 500 Index) has declined over the past three years**, reflecting rising interest rates versus the near-0% rate environment in 2021 and 2022. Also, much of the increased valuation for the S&P 500 was due to sharply higher share prices for a small group of stocks linked with artificial intelligence -- e.g., Microsoft, Apple, Nvidia, Alphabet and Amazon.



Note: Market values as of the close of business March 25, 2025. Refer to Slide 46 for composition of the CDMO index.
Source: S&P Global Intelligence and Bourne Partners

Selected Recent CDMO Acquisitions (1 of 3)

The volume of CDMO deal activity has been relatively soft in 2023 and 2024. That said, valuations have remained very strong, averaging ~5.0x revenue and ~18.2x EBITDA over the past four years. This includes the acquisitions of Catalent at ~22.9x EBITDA and Avid Bioscience at ~7.3x revenue -- highlighting the importance of fully-scaled platforms.

Date	Target	Acquirer	Commentary
Feb-2025	Pii Pharmaceutics International Inc.	JABIL	Early stage, clinical, and commercial volume aseptic filling, lyophilization, and oral solid dose manufacturing
Feb-2025	Avid Bioservices	Ampersand	Avid Bioservices was a publicly-traded CDMO focused on development and CGMP manufacturing of biologics
Jan-2025	pci Pharma Services	KKR / Blue Owl	Packaging, clinical trial support, and supply chain solutions with locations in the US, Europe, and Asia
Dec-2024	Catalent	novo holdings	Catalent was a publicly traded end-to-end CDMO with manufacturing sites primarily in the United States and Europe
Dec-2024	bormioli pharma	GERRESHEIMER	Glass and plastic packaging as well as closure solutions for the pharma, biotech and cosmetics industries
Oct-2024	FAMAR	Elements Capital Partners / Metric Capital Partners	A European CDMO specializing in the manufacturing of a wide range of pharma, cosmetic, and consumer products
Sep-2024	Biovectra	Agilent	Canadian manufacturer of biologics, active pharmaceutical ingredients, and other molecules for targeted therapies
Aug-2024	Cellipont Bioservices	Great Point Partners / HealthQuest Capital	Dedicated production of cell therapies offering development, analytical services, to large-scale commercial manufacturing
Jul-2024	Genuone Sciences	Macquarie	Small-molecule drug research and development, high-quality large-scale production, and other services

Selected Recent CDMO Acquisitions (2 of 3)

The volume of CDMO deal activity has been relatively soft in 2023 and 2024. That said, valuations have remained very strong, averaging ~5.0x revenue and ~18.2x EBITDA over the past four years. This includes the acquisitions of Catalent at ~22.9x EBITDA and Avid Bioscience at ~7.3x revenue -- highlighting the importance of fully-scaled platforms.

	Date	Target	Acquirer	Commentary
■	Jun-2024	MEDIVANT HEALTHCARE	1315 CAPITAL	503B outsourcing of sterile injectables to hospitals and other healthcare providers in nationwide (in 47 states)
	Jun-2024	CPL	Aterian INVESTMENT PARTNERS	Canadian based CDMO focused on non-sterile liquid and semi-solid dosage forms with 15 of the top 20 pharma companies
	Jun-2024	Bray Healthcare	ETHOS PARTNERS	U.K.-based manufacturer of pharma and medical products with a focus on skin and wound treatments and women's health
	May-2024	Maiva	InvAscent Morgan Stanley	Manufacturer of sterile solutions such as prefilled syringes, cartridges, and bags
	Apr-2024	SOCIETAL CDMO	core Rx	U.S. based CDMO focused on pre-Investigational New Drug (IND) development, commercial manufacturing, and packaging
■	Jan-2024	Afton Scientific	ACP	Aseptic fill-finish for drugs from pre-clinical to commercial-scale manufacturing across various therapeutic areas
■	Jan-2024	SUMMIT BIOSCIENCES INC.	Kindeva DRUG DELIVERY	CDMO focused on the unit dose nasal spray market with nine facilities across the United States and the United Kingdom
	Nov-2023	FORGE BIOLOGICS	Eat Well. Live Well. Aji AJINOMOTO	Viral vector and plasmid CDMO and clinical-stage therapeutics company from a custom-designed cGMP facility in Ohio
	Oct-2023	BioPharma Solutions	Advent	A unit of Baxter International with sterile manufacturing, parenteral delivery systems, and customized support services

■ = Bourne Partners Advised Transaction

Selected Recent CDMO Acquisitions (3 of 3)

The volume of CDMO deal activity has been relatively soft in 2023 and 2024. That said, valuations have remained very strong, averaging ~5.0x revenue and ~18.2x EBITDA over the past four years. This includes the acquisitions of Catalent at ~22.9x EBITDA and Avid Bioscience at ~7.3x revenue -- highlighting the importance of fully-scaled platforms.

Date	Target	Acquirer	Commentary
May-2023	bpifrance	L-GAM	Specialized in the industrial manufacturing of microorganisms for customers in the United States and internationally
Apr-2023	Pyramid Labs	Audax Private Equity	Formulation development, lyophilization, aseptic fill-finish of biologics, and other analytical and stability services
Oct-2022	metrics contract services	Catalent	Full service CDMO focused on integrated oral solid formulation development, manufacturing, and packaging
Aug-2022	TAPEMARK	LTS TRANSDERMAL. MARKETLEADER.	Development and manufacturing of transdermal, oral film, and topical drug delivery systems
Jan-2022	RITEDOSE	novo holdings	Blow-fill-seal(BFS) manufacturing of small fill volume pharmaceutical unit dose sterile and non-sterile liquids
Dec-2021	Frontida	ADARE PHARMA SOLUTIONS	Development and manufacturing of immediate and controlled-release oral solid dose, powder, and liquid products
Dec-2021	QUAYPHARMA	SGS	U.K.-based CDMO focused formulation research and development services as well as dosage form design
Jul-2021	Pharmathen	PARTNERS GROUP	Advanced drug delivery technologies for complex generic pharma products, including "sustained release" technologies
Feb-2021	Recipharm	ARDIAN EQT	Specialty CDMO services, including high-potency small molecules, lyophilization, pre-filled syringe tech and mRNA

= Bourne Partners Advised Transaction

Appendix: Bourne Partners Overview

Bourne Partners Overview

Since 2001, Bourne Partners has been offering a unique perspective and unmatched expertise while remaining highly focused on fulfilling the needs of established healthcare and life sciences companies across the globe

Our Passion

*"Working with **great people** and **great companies** to achieve **extraordinary results**."*

Highly-Focused Firm

Therapeutics | **Pharma Services** | **Healthcare Services**

Bourne Partners Investment Banking

Mergers & Acquisitions	
Sell-Side Advisory	*Buy-Side Advisory*
Company & Product Focus	*$100M - $1B+ Enterprise Value*
Capital Advisory Services	
Equity Capital Raising	*Debt Capital Raising*
Alternative Financing Options	*$100M+ Capital Raises*

Value-Add Advisors with a Global Reach

$15B+
Transaction Value

15
Years of Average Tenure at Bourne[1]

25+
Year Track Record

Six
Continents Reached

1) Average Tenure at Bourne: Director and Above

Research and Thought Leadership at Bourne Partners

Donald Hooker, CFA

Director of Research

Over twenty years of experience as a publishing sell-side equity analyst at UBS, Morgan Stanley, KeyBanc Capital Markets, and Capital One, among others

Extensive background in healthcare services, pharma services, and healthcare information technology

Joined Bourne Partners in July 2024 to build out a research function

Morgan Stanley

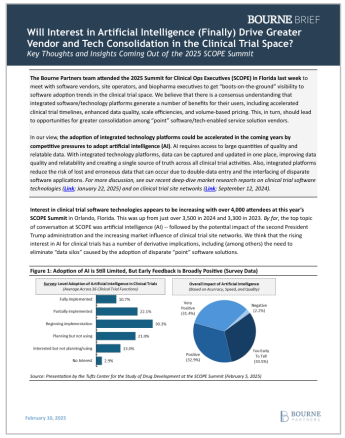
UBS

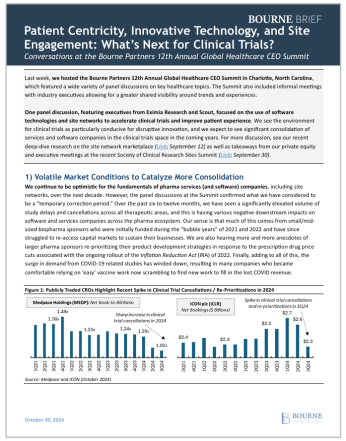
KeyBanc Capital Markets

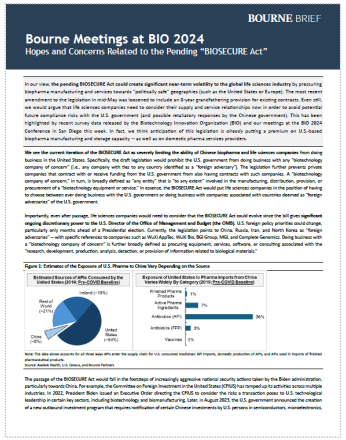
Capital One

The Bourne Partners Perspective

With 20+ years of exclusive industry and capital markets coverage, we are committed to providing insights to clients. We provide cutting-edge thought leadership on all things Pharma, Pharma Services, Healthcare Services, and Consumer Health.







Sector Expertise and Dedicated Coverage Professionals

Therapeutics

Representative Focus Areas

- Commercial-Stage Specialty & Rare Disease Biopharma Therapeutics
- Generic Pharma
- Legacy / Established Brands
- 505(b)(2)
- De-Risked Clinical Stage Biotech
- Cell & Gene Therapies
- Medical Devices

Representative Solutions

- Public & Private Sell-Side M&A
- Debt & Equity Financing
- Synthetic Royalty / Revenue Interest Financing
- Royalty Monetization
- Priority Review Voucher (PRV) Monetization & Financing

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Pharma Services

Representative Supply Chain Services

- Full-Service & Specialty CMOs & CDMOs
- Biostorage, Distribution & Logistics Services
- Commercial Lab & Analytical Services
- Contract Packaging & Labeling
- Manufacturing Consulting & Strategy Services

Representative Clinical Services

- Full-Service & Specialty CROs
- SMOs & Clinical Research Site Networks
- Patient Recruitment & Engagement
- Research Site-Enabling Services & Technologies
- Clinical Regulatory Consulting & Strategy Services

Representative Commercialization Services

- HCP, Patient & Omnichannel Engagement
- Market Access & Pricing, HEOR, RWE
- Medcomms & Healthcare Marketing / Advertising
- Medical & Regulatory Affairs & Pharmacovigilance
- Patient Support & Hub Services

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Healthcare Services

Representative Healthcare Services

- Post Acute Care
- Behavioral Health
- Managed Care
- Physician Practice Management
- Alternate Site

Representative Outsourced Services

- Distribution
- Home Medical Supplies & DME
- Labs & Lab Services
- Staffing
- Virtual Care-Enablement & Provider Technologies

Representative Pharmacy Services

- Infusion Services
- 503A Compounding Pharmacy
- 503B Hospital Outsourcing
- Specialty and Retail Pharmacy
- Medication Management & Adherence

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Founder & CEO

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Sr. Managing Director

Aaron Olson
Managing Director

Xan Smith
Managing Director, Sponsor Coverage

Todd Bokus
Director

Robert Stanley
Director

Carson Riley
Director

Don Hooker
Director, Head of Research

Transaction Execution Team

Vice Presidents



Associates




Analysts






Senior Advisors & Administration

John Chiminski
Senior Advisor

Paul Campanelli
Senior Advisor

Matt Bullard
Senior Advisor

Martin Zentgraf
Senior Advisor

Bruce Montgomery
Senior Advisor

Minor Hinson
CIO, BPSC

Chris Inklebarger
COO, General Counsel

Calli Lewis
Chief of Staff

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