2024 / 2025

2024 GLOBAL BIOPHARMACEUTICAL M&A AND VC INSIGHTS

DECEMBER 2024

ALVAREZ & MARSAL

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INTRODUCTION

Mergers and acquisitions (M&A) activity in 2024 within the biopharmaceuticals sector indicate a moderately-subdued level of dealmaking relative to 2023, as dealmakers generally responded to economic and geopolitical headwinds through engaging in smaller-sized transactions with a focus on novel, pre-clinical therapeutics as companies continue to pursue longer-term value creation through acquiring innovation.

Venture capital-led deal activity has generally been more aggressive, with significant funding centered on early-stage financing deals involving Artificial Intelligence (AI) capabilities and Obesity-focused clinical assets. Of note, VC-backed Biotech exits through initial public offerings (IPOs) have nearly doubled in volume from 2023.

For 2025, we project deal activity in 2025 to be robust. While companies will need to balance dealmaking with market forces – including high interest rates, geopolitical and trade uncertainty, and recent activist shareholder pressure – we expect life sciences companies to harness M&A as a catalyst for achieving innovation, mitigating against rapidly approaching loss of exclusivity (LOE) timelines for top-selling drugs, and ultimately optimizing portfolio value.

Table 1: Top Pure-Play Biopharma Corporate M&A Deals[1] in 2024 Through Q3

ACQUIRER	TARGET	DEAL VALUE ($B)	QUARTER	ACQUIRER DEAL RATIONALE
Vertex Pharma	Alpine Immune Sciences	**4.9**	Q2	Bolster Immunology and Inflammation pipeline
Gilead Sciences	CymaBay Therapeutics	**4.3**	Q1	Expand liver disease portfolio
Eli Lilly	Morphic Holdings	**3.2**	Q3	Immunology & inflammation focus
Merck	EyeBio	**3.0**	Q2	Access to late-stage ophthalmic
Novartis	MorphoSys	**2.9**	Q1	Expands on oncology strategic focus
Ono Pharma	Deciphera Pharma	**2.4**	Q2	Expand pipeline and accelerate globalization
AstraZeneca	Fusion Pharma	**2.0**	Q1	Expand oncology pipeline
Johnson & Johnson	Ambrx Biopharma	**2.0**	Q1	Acquire novel ADC platform
Biogen	Human Immunology Biosciences	**1.8**	Q2	Bolster late-stage immunology pipeline
Genmab	ProfoundBio	**1.8**	Q2	Complements existing ADC platform
Novartis	Mariana Oncology	**1.7**	Q2	Expand RLT pipeline with newer modality
Sanofi	Inhibrx	**1.7**	Q1	Expands existing rare disease and I&I presence
GSK	Aiolos Bio	**1.4**	Q1	Expand respiratory biologics portfolio for asthma
Merck	Curon Biopharma	**1.3**	Q3	Access to bispecific therapeutic
Boehringer Ingelheim	Nerio Therapeutics	**1.3**	Q3	Strengthen immune-oncology pipeline
Johnson & Johnson	Yellow Jersey Therapeutics	**1.2**	Q2	Access to bispecific therapeutic
Organon	Dermavant Sciences	**1.2**	Q3	Increase women's health focus
Otsuka America	Jnana Therapeutics	**1.1**	Q3	Complementary drug discovery platform
Novo Nordisk	Cardior Pharma	**1.1**	Q1	Strengthen pipeline of cardiovascular programs
AstraZeneca	Amolyt Pharma	**1.0**	Q1	Expand late-stage rare disease pipeline

1. Excludes PE-led deals, non-drug-developer focused deals, terminated deals and minority acquisitions

Source: GlobalData

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RECAP OF 2024: 6 KEY INSIGHTS

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M&A activity has been subdued relative to 2023 with companies prioritizing growth and innovation

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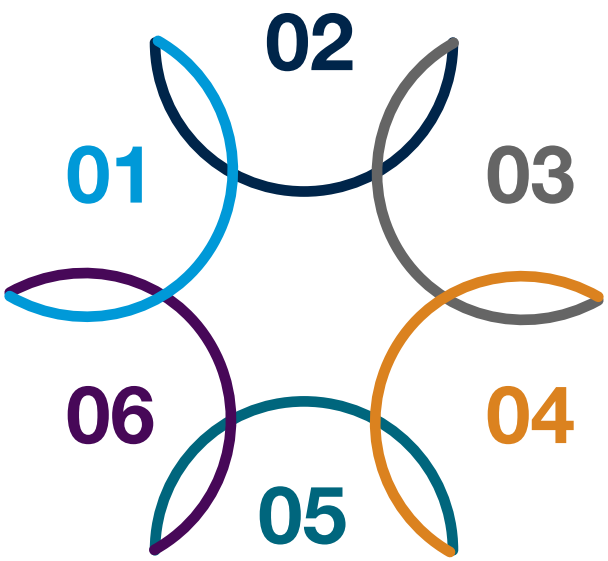
Acquirers continue to target pre-clinical therapeutics within Oncology and central nervous systems (CNS) therapeutics



03.
Cell and gene therapies (CGT) and anti-drug conjugates (ADCs) continue to remain attractive investment targets, with mRNA therapies gaining traction

04.
VC dealmaking continues to remain steady, with 2024 deal volume tracking similarly to 2023

05.
VC deals continue to concentrate around early-stage funding, reflecting a focus on novel innovative technologies

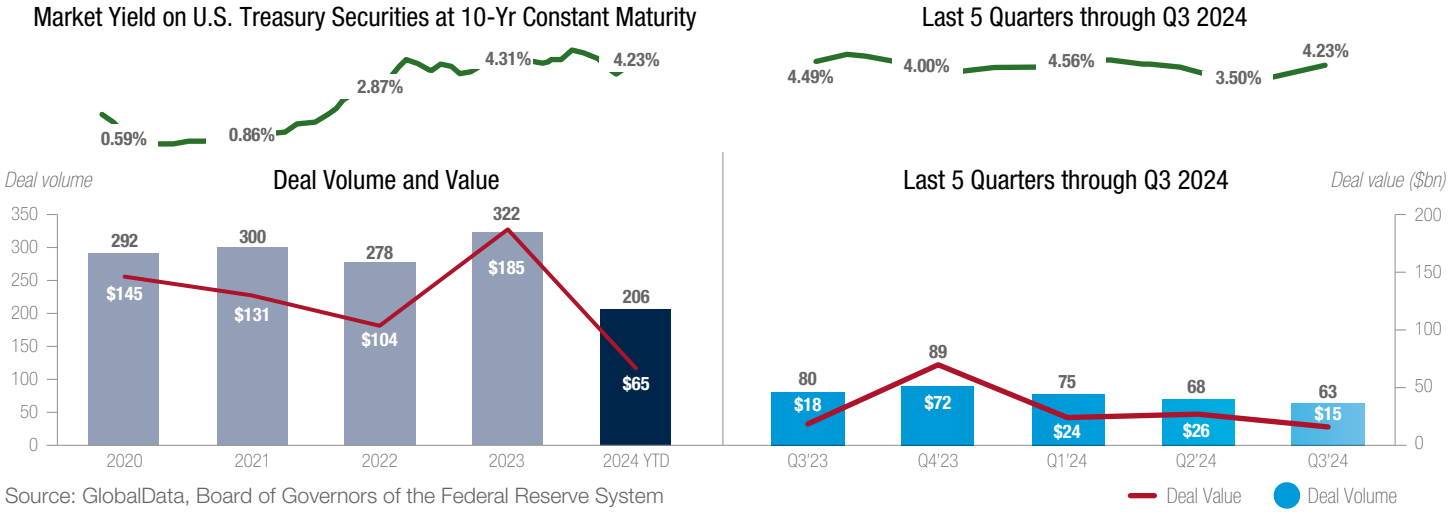
06.
Biotech IPOs in 2024 to date have nearly doubled in volume relative to 2023, indicating acclimation to interest rates generally holding steady

02
M&A OBSERVATIONS FROM 2023 TO 2024

The biopharmaceutical M&A market has fluctuated in recent years as dealmakers began to navigate the post-COVID-19 environment facing prolonged high interest rates and challenges within supply chains, leading to subdued activity in 2022. With 2024 nearly complete, overall deal activity has been subdued: through Q3, analysis indicates 206 pure-play biopharmaceutical deals, equating to 64% of the reported deal volume from 2023. Transaction values in aggregate show a substantial decrease in 2024, with total deals through Q3 equating to 65B USD in value, or only 35% of total reported deal value from 2023.

High interest rates, as demonstrated by the inverted yield curve for Treasury securities over the past 2 years, have played a prominent role in curtailing dealmaking. Inverted yield curves have historically been regarded as a predictor of recession; however, recent trends indicate a flattening curve, which could assuage dealmakers against recessionary concerns heading into 2025.

Figure 1: U.S. Interest Rates and Corresponding Deal Volume and Deal Value (2024 YTD)



Source: GlobalData, Board of Governors of the Federal Reserve System

The data indicates the continuation of a recent trend: companies are seemingly pursuing smaller deals. 2024 to date has not entailed any traditional "megadeals", with Vertex's acquisition of Alpine for 4.9B USD constituting the largest corporate pure-play biopharmaceutical deal to date in the calendar year. In contrast, 2023 featured Pfizer's acquisition of Seagen for 43B.

The gravitation towards smaller-scale transactions can be explained by a number of factors — most notably a pursuit of pre-clinical novel technologies to refresh pipeline portfolio and ultimately drive long-term growth and innovation. Innovation remains the predominant strategic goal for large multinational pharmaceutical companies, who continue to face portfolio risks arising from rapidly approaching LOE of blockbuster drugs.

Why Smaller Transactions?

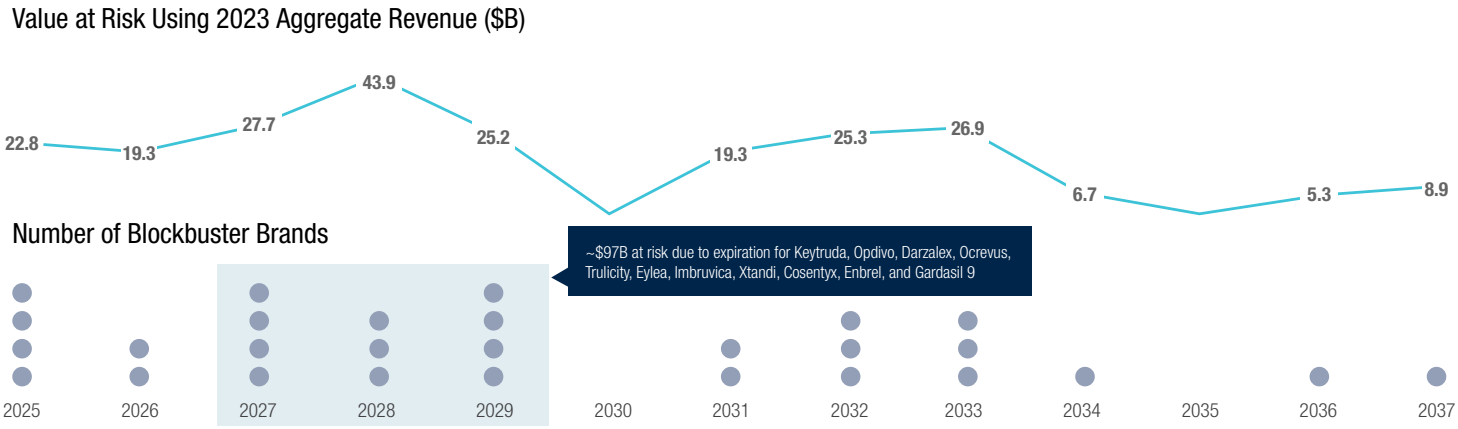
Innovation
Acquirers have targeted early-stage therapeutics over established, commercialized assets to drive long-term value.

FTC Scrutiny
Complex transaction structures generally result in increased scrutiny by the US Federal Trade Commission, often leading to prolonged deal timelines.

Integration Risks
Ability to realize value from larger-scale transactions depends on the acquirer's ability to integrate complex operations, human capital and additional assets effectively.

Macroeconomic and Geopolitical Uncertainty
High U.S. interest rates and current political/trade uncertainty can deter dealmakers from larger-scale transactions.

Figure 2: Loss of Exclusivity Timeline for Blockbuster Drugs Through 2037 (2023 Top Sellers)



Source: GlobalData

In addition to focusing on innovation, dealmakers are prioritizing mitigating deal risk. Pursuing smaller-scale deals can help with reducing integration risk associated with harmonizing complex operations, human capital, and other acquired assets or capabilities which typically generate numerous obstacles across pathways to realize value. Our observations also reveal another avenue dealmakers are pursuing to mitigate risk: exploring creative ways to structure deals. Acquirers are increasingly structuring deals to incorporate earn-outs and payments around achievement of select milestones, typically within research and development (R&D). A notable example in 2024 was Novartis's 835M USD acquisition of IFM Due, where 89% of the deal value is tied to milestone payments.

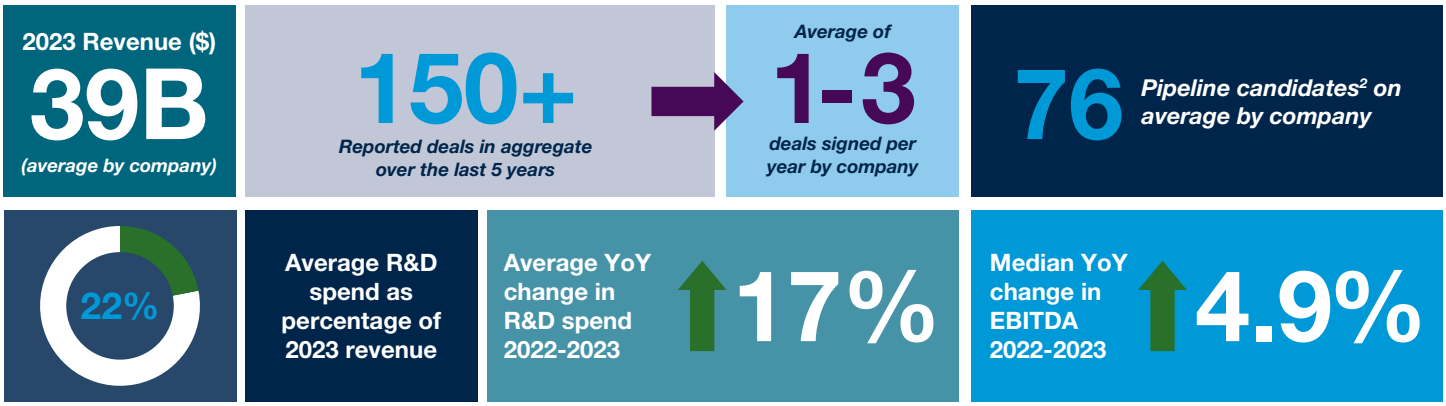
Table 2: Notable Recent Transactions with Earnout Structures

ACQUIRER	TARGET	DEAL VALUE	EARNOUTS (% DEAL VALUE)
Biogen	HI Biosciences	**$1.8B**	36%
GSK	Aiolos Bio	**$1.4B**	29%
Novartis	IFM Due	**$835M**	89%
Telix	Iso Therapeutics Group	**$13M**	38%

Companies may also pursue non-M&A channels for engaging with external biotechnology companies, for example through collaboration, co-development or other financing agreements. For example, in Eli Lilly's collaboration agreement with AI Biotech Isomorphic Labs (a subsidiary of Alphabet) valued at 1.7B USD, Lilly will provide an upfront payment of 45M USD, with award of the additional 1.3B USD to Alphabet tied to performance-based milestones. For Lilly, the primary benefit of the agreement would be acquiring access to novel AI technologies without undertaking the risks associated with a traditional deal; however, value upside could be limited as other life sciences companies, such as Novartis, have similar agreements with Isomorphic. Therefore, Lilly may not be in optimal position to acquire full rights to Isomorphic's capabilities and could ultimately forgo an opportunity to gain a longer-term competitive advantage.

WHO'S MAKING THE DEALS?

Figure 3: 2023 Top 20 Life Sciences Dealmakers[1] By The Numbers

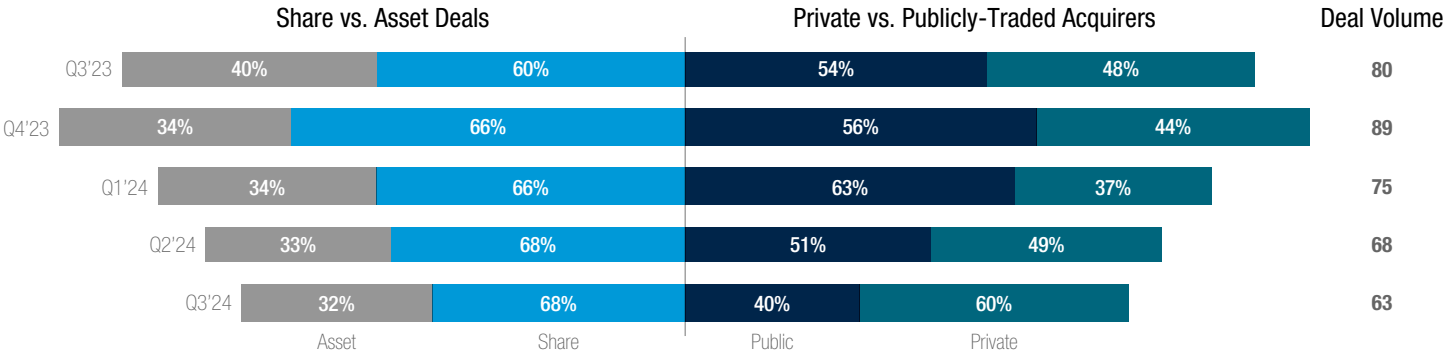


Source: GlobalData, CapIQ, Company filings, A&M analysis
1. Drug manufacturers by 2023 revenue
2. Based on 2023 information across Discovery, Phase I-IV, and Regulatory phases

A closer look at the top 20 pharmaceutical companies by 2023 revenue engaging in deal activity over the past five years reveals that on average, a large pharmaceutical company will tend to make approximately one to three significant acquisitions per year. In addition, these companies have undertaken on average, a 17 percent increase in R&D spend from 2023, and have experienced a median increase of 4.9% in EBITDA over the prior year. While the correlation between R&D spend and EBITDA is not fully linear, an examination of public statements from dealmakers over the past year indicates a common theme of utilizing M&A to drive R&D innovation and thereby helping to mitigate future portfolio LOE risks.

For Q3'24, private company-led transaction volume outweighed public company-led deals. A notable example involves Candid Therapeutics and its three-way merger with Vignette Bio and TRC 2004. The deal featured two bispecific lead assets, one from each company, for autoimmune indications as part of Candid's official launch in September 2024 (Kush, #10). We expect public company deal activity to increase and likely recapture deal volume share heading into 2025.

Figure 4: Distribution of Acquirer and Deal Profiles Q3'23 – Q3'24

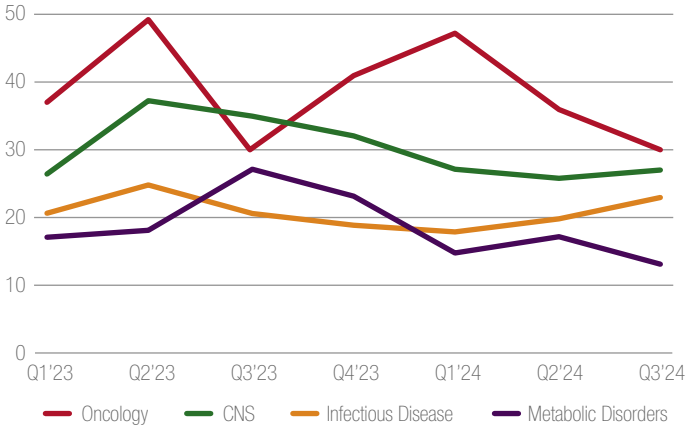


Source: GlobalData, A&M Analysis

Through 2024, companies have transacted primary through equity or share deals. Despite the trend towards smaller scale deals, companies generally remain hesitant to transact fully bespoke product assets, likely due to separation challenges for sellers, and the limited time-value return from undertaking associated carve-out and separation activities. Bespoke product-asset deals (for example, transactions involving specific SKUs, Market Authorizations, or Product Families) are more conducive to Business Development & In/Out Licensing deals across parties which entail the ability of a licensee to develop, commercialize, or distribute product assets in exchange for a royalty or other fee arrangement to the licensor, and can be executed in a much quicker timeframe relative to a deal.

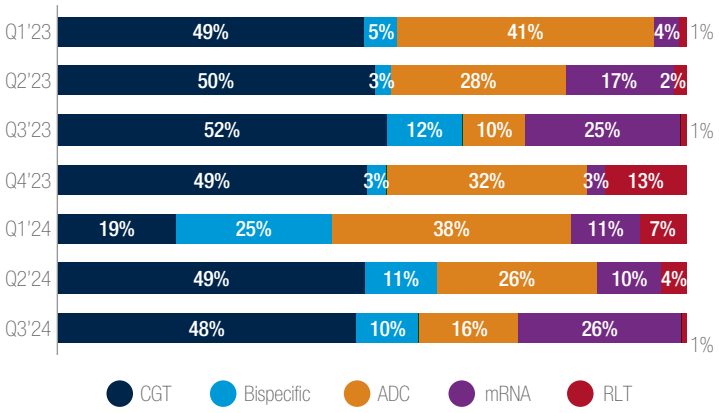
WHAT ARE COMPANIES INVESTING IN?

Figure 5: Top 4 Therapeutic Areas Deal Volume



Source: GlobalData, A&M Analysis

Figure 6: Share of Targeted Innovative Drug Technology M&A



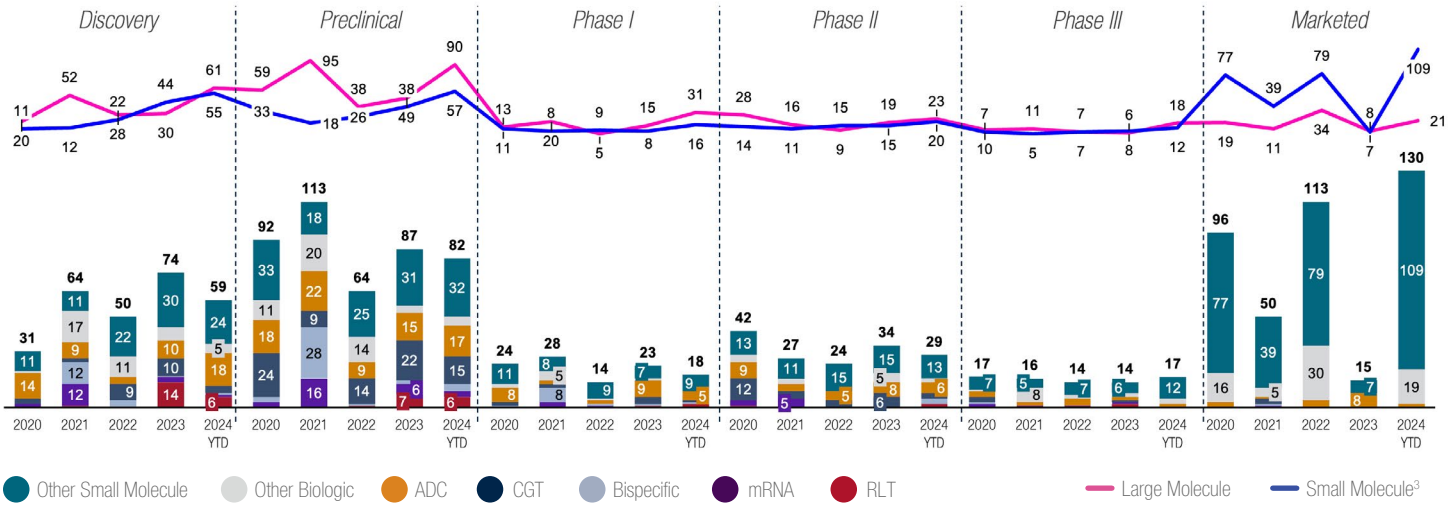
Source: GlobalData, A&M Analysis

A consistent trend across recent years, life sciences companies continue to utilize M&A to acquire Oncology-focused assets and capabilities. Since Q1 2023, analysis indicates 270 transactions identified as deals between drug developers and biotechs within the Oncology space, equating to approximately 39 deals per quarter on average. Dealmakers continue to seek presence within the space, as global spending for cancer medicines totaled 223B USD in 2023 (13% increase from 2022) and projects to total 409B USD in total spending by 2028 (Global Oncology Trends, #6). Combined with the continuing global increase in cancer incidence among patients, the oncology market in theory projects to maintain longer term investor interest. One anticipated challenge could be market oversaturation, with many companies active in the oncology space with either commercialized branded medicines, generics, or pipeline candidates in development.

2024 deal activity also indicates an increase in CNS deals, with analysis indicating 210 transactions since Q1 2023 within the space. Similar to Oncology, the CNS space is valued at 133.8B USD as of 2023 with an increasing patient population seeking treatment across brain and spine disorders including Alzheimer's, Parkinson's, epilepsy and multiple sclerosis, positioning the space as attractive for investments and deals (Gores and Lutzmayer, #7).

Of note, Cell and Gene Therapy (CGT) technology deals continues to account for nearly 50% of deals within the past two quarters. Due in part to the saturated nature of the oncology market, life sciences companies are attempting to branch out across differentiated modalities harnessing CGT and precision-targeted drugs, aiming to meet the increasing demand for personalized and effective cancer treatments. Additionally, CGT can provide new treatment alternatives for patients who may lack treatment options for non-oncology indications — such as autoimmune disease, HIV/AIDS and scleroderma. Life sciences companies have historically faced challenges in bringing CGT treatments to market due to resources required to drive manufacturing, developmental and tailored patient clinical trials.

Figure 7: Drug Technology Deal Volume[1] by Clinical Development Stage Across Top 30 Biopharmas[2]



Source: GlobalData, A&M Analysis

1. Deal volume tabulated by individual product and drug technology-related assets disclosed as part of transaction communications
2. Top 30 biopharmaceutical companies ranked by FY2023 revenue
3. Small molecule includes Other Small Molecule and RLT (Radioligand Therapies) while Large Molecule includes the remaining drug technologies

Clustering deal activity by development stage shows increased recent deal activity within discovery or pre-clinical development stages, along with a generally downward trend through 2024 for deals involving in-market products. This is further indicative of the shift in strategic priorities among the top life sciences companies from short-term revenue accretion to longer-term innovation.

Companies are also still in the early stages of pivoting from small-molecule to large-molecule drugs. Small-molecule drugs, generally organic chemical compounds with low molecular weight, have historically maintained a robust market. In 2023, small-molecule drugs accounted for $785 billion of all drugs sold, or 58 percent of market share relative to large-molecule drugs (Van Arnum, #16). Furthermore, 69 percent of new drug approvals by the FDA in 2023 were small-molecule approvals (Cavazzoni, #4). However, the longer-term outlook for small-molecule drugs presents a different picture, where increasing regulatory scrutiny, competition from generics and increasing demand for targeted precision medicine therapies have influenced investment toward larger-molecule drugs — complex biologics with active substances consisting of or derived from living organisms — evidenced by the 14 percent growth in biologic drug sales from 2018 to 2023 (Van Arnum, #16). The future of small-molecule drugs may also be impacted by the passage of the 2022 Inflation Reduction Act (IRA).

An interesting data point observed is that there appeared an uptick in small-molecule-related deal activity in 2024, with 109 small-molecule deals involving in-market drugs reported through Q3 2024. A closer look at the data indicates a likely one-off occurrence, as the deals in question stemmed from non-U.S. companies. For example, in September 2024, India-based Aurobindo Pharma agreed to acquire GLS Therapeutics, a producer of generic Oncology drugs. While we do not anticipate major short-term movement within the overall small-molecule market, continued small-molecule deal activity involving generics will be an area to monitor heading into 2025.

DEAL SPOTLIGHT: BOREALIS BIOSCIENCES

On August 22, 2024, Novartis in partnership with Versant Ventures announced the launch of Borealis Biosciences, an independent, discovery-stage focused on developing next-generation xRNA-based medicines for kidney diseases.

NOTEWORTHY OBSERVATIONS

Unique Deal Structure

Separation of Novartis's Chinook Therapeutics business previously acquired in 2023 coupled with 150M USD in Series A funding from Novartis and Versant Ventures.

Access to Novel RNA Therapeutics

Novartis will have the option to acquire two future development-ready programs from Borealis, with Borealis eligible for up to 750M USD in clinical and regulatory milestones.

Corporate Biopharma and Venture Capital

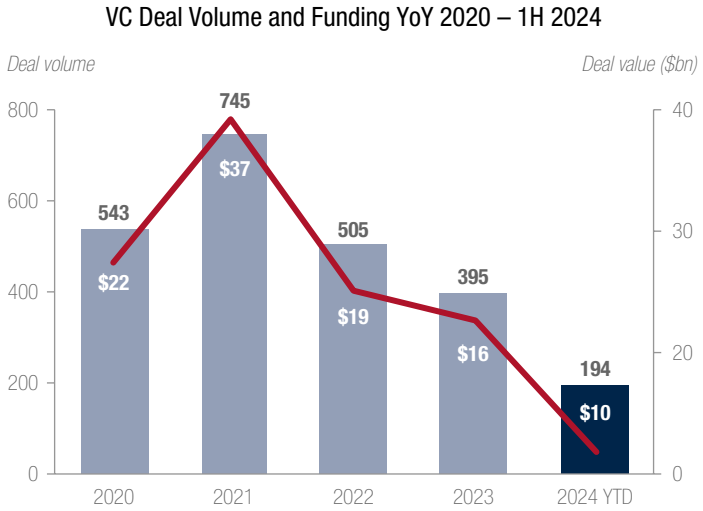
With corporate biopharmas and VCs often at odds competing for innovation, this deal is a notable example of how collaborative partnership can open new dealmaking opportunities.

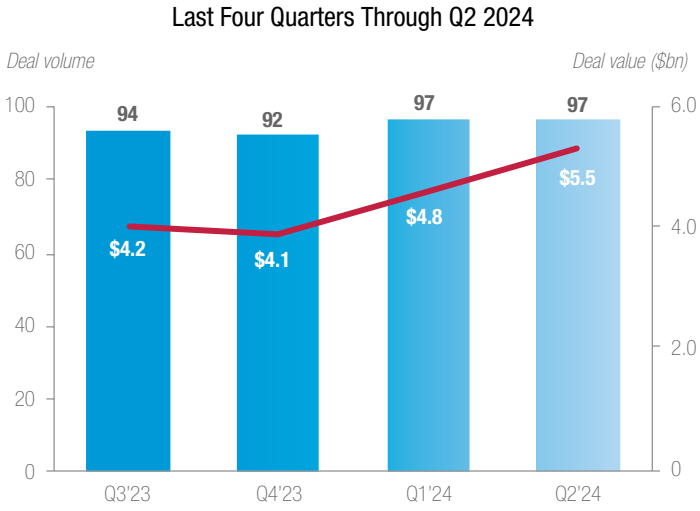
Refocus Capabilities and Preserve Culture

By separating select employees and the legacy Chinook research facility, Novartis can streamline R&D operations; conversely, Borealis can preserve an entrepreneurial research culture as an independent company.

03
VENTURE CAPITAL FUNDING TRENDS

Figure 8: VC Financing Deal Value and Volume (through 1H 2024)





Source(s): GlobalData, Pitchbook, A&M Analysis

Venture capitalists within biotech convey a continued interest in pursuing innovation and early-stage investments. Oftentimes, VC activity can serve as a barometer for M&A activity, as strategic priorities from VCs tend to reflect M&A sentiment expressed by corporate development teams.

Total VC deal volume in 2024 projects to be in line with 2023 with 194 VC deals announced through Q2 2024 — roughly 50% of 2023 totals. However, average value per deal (53M USD) has increased over the prior year, interestingly in contrast with average M&A deal value which decreased. While M&A dealmakers generally pursued smaller deals to help mitigate risk, VCs are opting for larger deals with loftier target valuations, indicating the market premium on innovation and long-term returns. A closer look at notable recent VC deal activity reveals why:

Table 2: Notable VC Deals through Q2 2024

COMPANY	FUNDING	STAGE
Xaira Therapeutics	$1.0B	Series A
Kailera Therapeutics	$400M	Series A
Formation Bio	$372M	Series D
Candid Therapeautics	$370M	Series A
Orbital Therapeutics	$270M	Series A
AltruBio	$225M	Series B
Capstan Therapeutics	$175M	Series B
Borealis Biosciences	$150M	Series A
Outpace Bio	$144M	Series B
Eyebio	$65M	Series A

Both Xaira Therapeutics and Formulation Bio received a combined $1.37 billion in VC funding earlier in 2024. Both biotech companies focus on AI-facilitated drug discovery, a domain monitored very closely by the life sciences industry and widely regarded as an area where AI enablement could generate monumental returns on capital and efficiency. The drug discovery process, which today relies on labor-intensive trial-and-error experimentation of molecular substances to gauge clinical responses, can take years to uncover potential candidates. Progressing a drug candidate through the development, regulatory approval and launch cycles can entail another 15 years. AI platforms and LLMs offer the potential to accelerate drug discovery by analyzing large volumes of data with greater efficiency and predicting drug compound efficacies with higher accuracy. This has naturally led to garnering widespread attention around the biotech VC community (Blanco-González et al., #3).

Figure 9: VC Deals by Funding Stage (YoY 2020 – 2023)

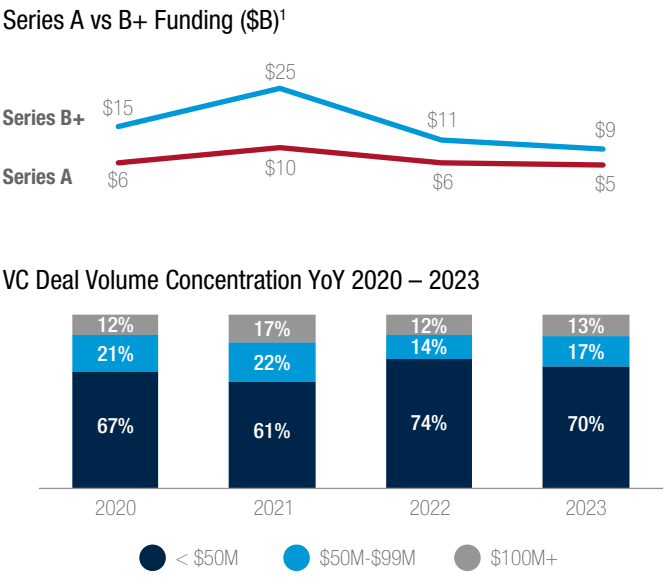
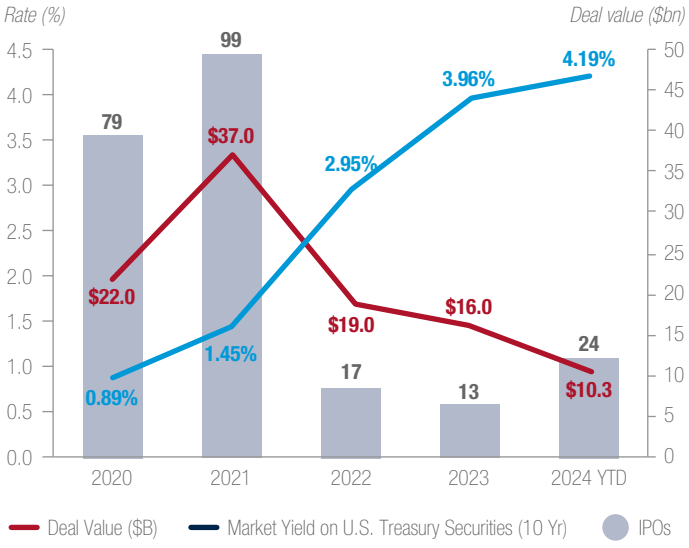
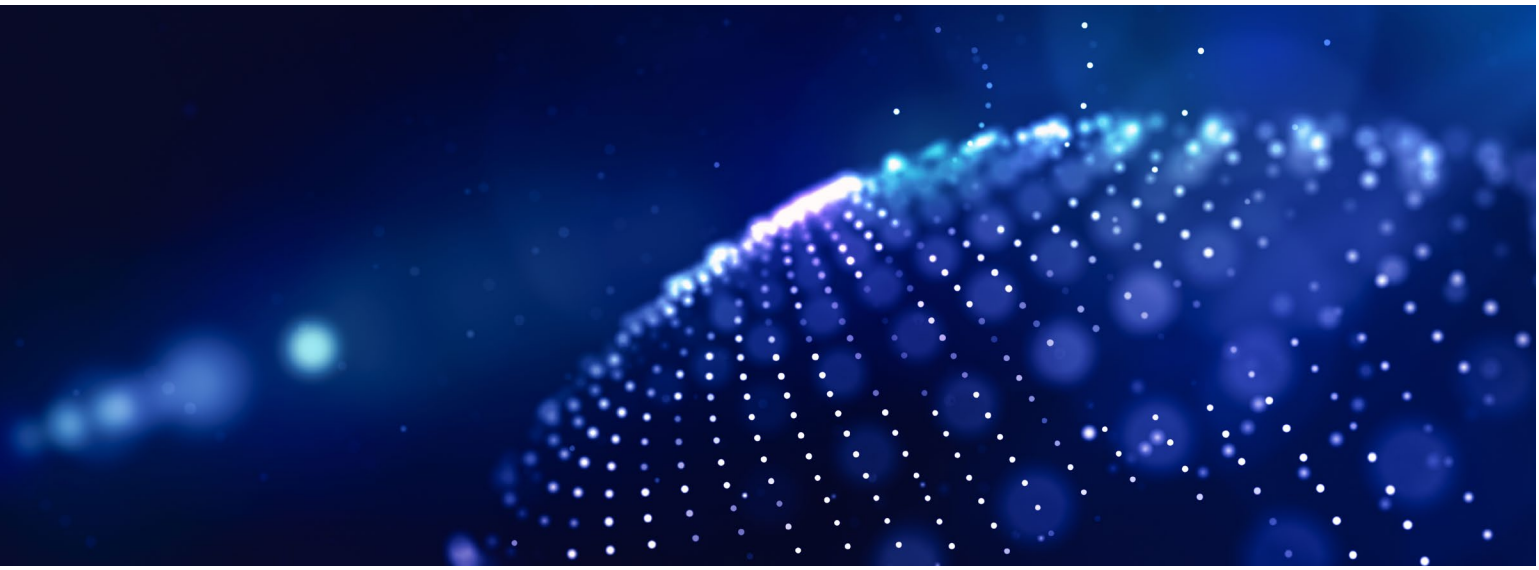


Figure 10: Impact of Interest Rates on VC Activity



1. Excludes VC deals with no identifiable round of financing

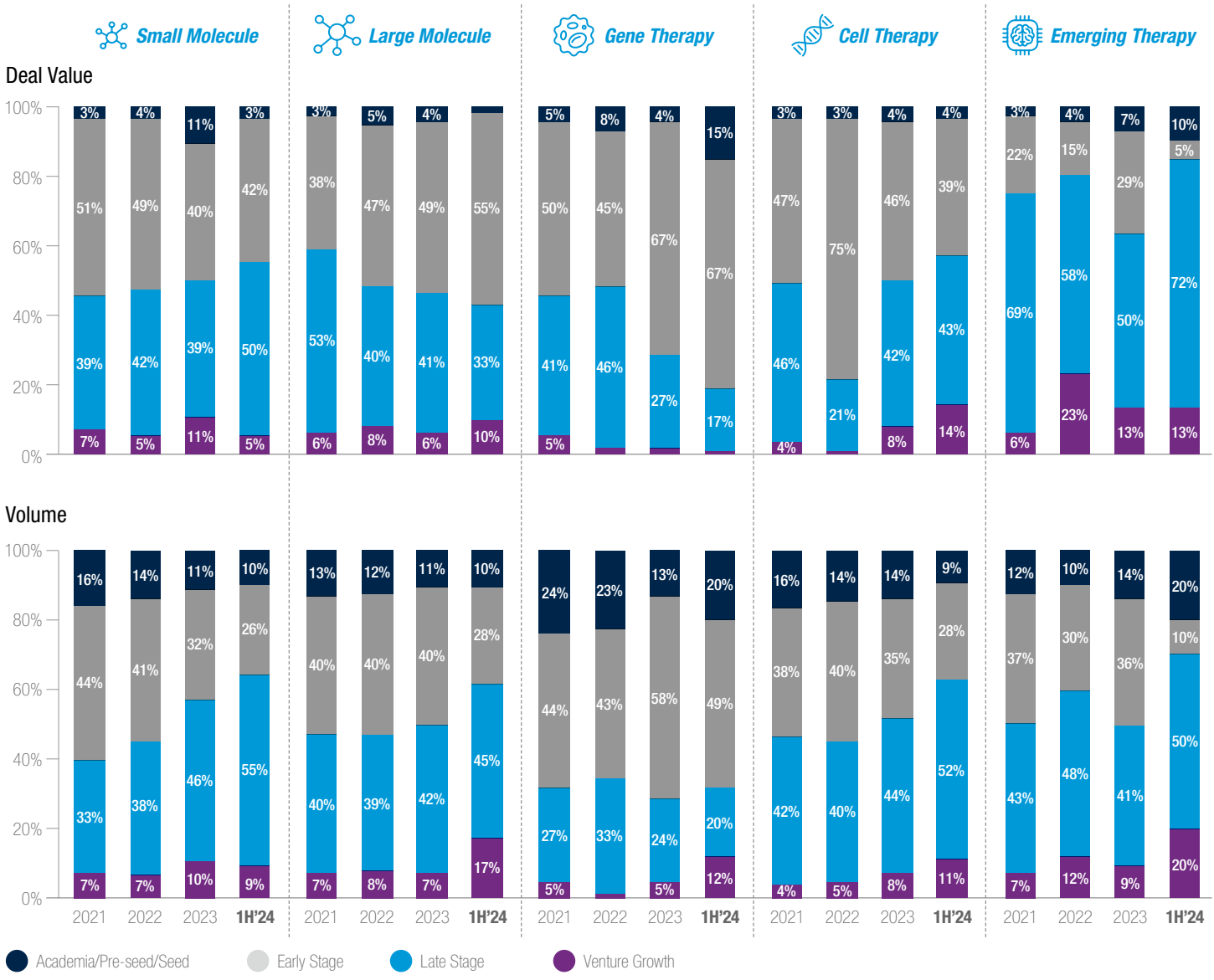
Source(s): A&M Analysis, Board of Governors of the Federal Reserve System, GlobalData and DealForma Database



Similar to M&A dealmakers, VCs continue to concentrate early-stage investments, often deploying capital as part of Series A funding to biotech startups. While still lower in aggregate relative to Series B and later VC deals through 2023, year-over-year data indicates a steady trend around Series A funding deals, with a 2B USD decline in Series B and later funding deals from 2022 to 2023. Furthermore, as expected with early-stage investment concentration, a majority of VC deals since 2020 entail funding rounds lower than 50M USD in value. As observed with M&A deals, VC deal trends reflect a similar shift away from small molecule assets.

For biotechs and VCs, IPOs are perceived as the more attractive exit path relative to M&A: an IPO can provide the capital raise to cater to VC objectives while allowing the biotech to maintain an independent, entrepreneurial culture. As shown in Figure 10, analysis indicates a decline in the number of biotech IPOs from 2021 through 2023, likely attributed to a corresponding increase in interest rates. However, 2024 data shows 24 IPOs reported through Q3, more than double the number in 2023. This may signify investor acclimation to rates continuing to hold steady, and we therefore expect biotech IPOs and VC deal activity to increase heading into 2025.

Figure 11: VC Deal Concentration by Stage Clustered by Therapeutic Category (%)



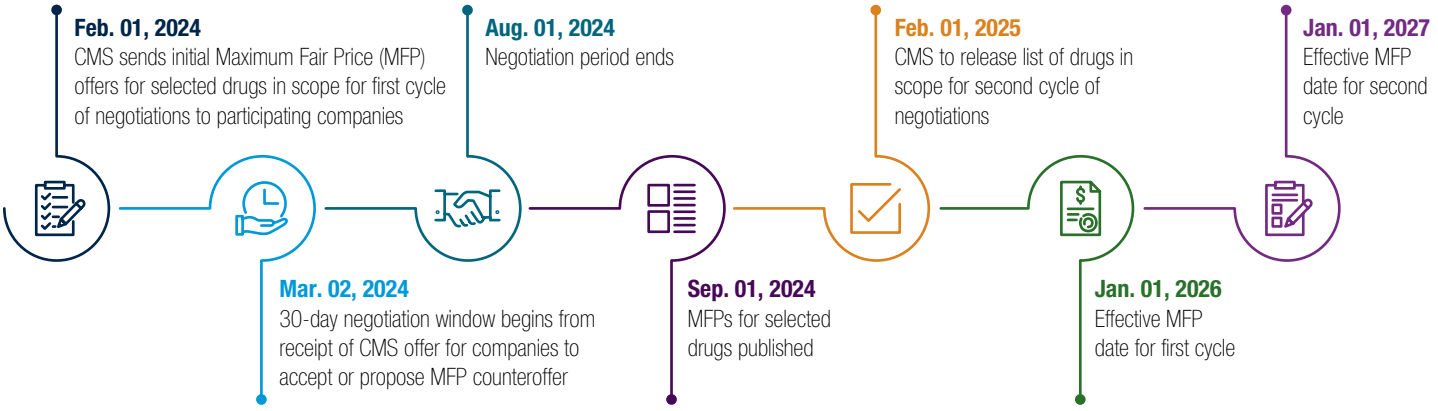
Source(s): PitchBook

04
DEEP DIVE: CONTINUED ROLE OF PUBLIC POLICY IN DEAL MAKING

In this section, we will examine three key public policy forces that project to influence dealmaking for the near-term future: the Inflation Reduction Act (IRA), US Federal Trade Commission (FTC) and the Biosecure Act.

INFLATION REDUCTION ACT AND DRUG NEGOTIATIONS: RECENT HISTORY

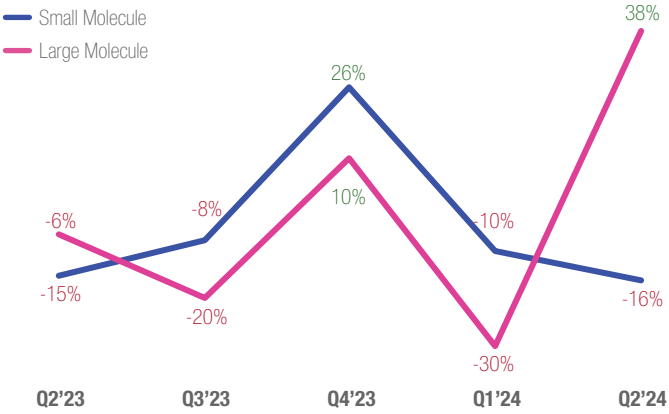
Part D Drug Negotiation: Latest Timeline



Source(s): Center for Medicare & Medicaid Services (CMS)

One of the core tenets of the IRA has been the Maximum Fair Price (MFP) effectuation, which would allow Centers for Medicare & Medicaid Services (CMS) to directly negotiate prices with drug manufacturers for certain drugs covered under Part B and D. In theory, MFP is designed to help increase affordability and accessibility to medicines by patients. However, the response from life sciences organizations may lead to the opposite: *market access may actually be exacerbated* as drug manufacturers rethink portfolio strategy in light of changes to drug economics.

Figure 12: Quarter-over-Quarter Percentage Change in VC Deal Volume (Q2 2023 – Q2 2024)



Source: PitchBook

An examination of VC trends across small and large molecule deals over a 5-quarter period from Q2 2023 through Q2 2024 shows a declining trajectory in small molecule-related VC deal interest, with a recent upward trend in large molecule activity. A catalyst for the decline could be a stipulation introduced as part of the MFP negotiations for a new "Medicare event horizon" where for newly launched drugs, economic lifecycle before MFP effectuates shortens to 9 years for small molecule drugs, and 13 years for large molecule drugs. For drugmakers, this time window essentially serves as a defacto LOE, and therefore has numerous implications:

- Drugmakers may opt to pursue a wide range indications when developing drug candidates to maximize total addressable market and may deprioritize candidates targeting indications that would address a smaller market.
- Acquirers may be dissuaded from the economics of new small molecule drugs given the disparity between the development cycle (typically 10-15 years) and the now limited time on market before MFP effectuates (9 years), particularly when drug sales tend to peak towards the tail of the lifecycle.
- With lower prices on branded drugs, competing generics could undergo further price erosion, creating additional economic deterrents for companies considering investment in generics or actively maintaining generics within existing portfolios. Reduced investment or market exits from generics could lead to drug shortages, ultimately conflicting with the patient accessibility goals originally contemplated by the legislation.

Starting January 1, 2026, the list of selected drugs in scope for the first cycle of negotiations will now have MFPs effective in the market, with drugs in the second cycle having MFPs effective starting 2027. For Part B drugs, MFPs would be effective in 2028. Life sciences companies have already begun to rethink portfolio strategy — for example, Novo Nordisk shifting current portfolio strategy towards positioning as a market leader in obesity over its heritage diabetes / insulin focus, and Novartis pivoting focus towards innovative pre-clinical gene therapies, in contrast with its history as a more diversified pharmaceuticals and generics company. With lower drug costs expected to maintain bi-partisan popularity through the incoming presidential administration, we expect continued criticality for life sciences companies to reevaluate pipeline candidates and ensure a focus on innovation to remain successful for the long term.

SELECTED DRUGS IN SCOPE FOR FIRST CYCLE	
DRUG	**DEVELOPER**
Eliquis	Bristol-Myers Squibb
Jardiance	Boehringer Ingelheim
Xarelto	Janssen Pharmaceuticals
Januvia	Merck & Co
Farxiga	AstraZeneca
Entresto	Novartis
Enbrel	Amgen
Imbruvica	Pharmacyclics
Stelara	Janssen Pharmaceuticals
NovoLog	Novo Nordisk

FTC REVIEW OF THE NOVO HOLDINGS-CATALENT TRANSACTION AND IMPLICATIONS ON VERTICAL INTEGRATION WITHIN LIFE SCIENCES

The U.S. FTC's guiding philosophy for antitrust regulation has historically provided the guardrails to protect consumer welfare. Could this change in 2025?

The FTC describes its mission as "protecting the public from deceptive or unfair business practices and from unfair methods of competition," and plays a vital role in shaping M&A activity across all major industry sectors as the agency strives to uphold competitive balance among businesses and market fairness for customers (FTC Mission, #5). The Life Sciences industry has witnessed acute involvement from the FTC to enforce antitrust law given the volume of M&A activity within the industry and the criticality of patient healthcare. As M&A still projects to serve as a core component of growth strategies for drug manufacturers, understanding the FTC's approach and outlook for potential vertical integrations will be crucial for life sciences companies.

NOVO HOLDINGS-CATALENT TRANSACTION OVERVIEW

On Feb. 5, 2024, Novo Holdings — the holding company and majority shareholder for the global pharmaceutical company Novo Nordisk — agreed to acquire the contract development and manufacturing organization (CDMO) Catalent in a transaction valued at $16.5 billion (Novo Holdings, #11). The impetus for Novo was to expand manufacturing capacity around Novo Nordisk's GLP-1 drug Wegovy, which recorded Q3 2024 sales of $2.5 billion — 81 percent higher than the same period in 2023 — positioning Novo Nordisk as a global leader in obesity (Q3 2024 Presentation 163, #13).

While drug developers have increasingly turned to contracting with outsourced pharmaceutical service providers, such as CDMOs like Catalent, as well as contract research organizations (CROs) to streamline costs, Novo has chosen to vertically integrate with a major CDMO. Because Catalent has existing third-party customer obligations with Novo Nordisk's competitors, concerns have been raised regarding the potential influence Novo could have on its competitors' ability to manufacture products produced at Catalent, thereby conveying the marketplace imbalance that could result from vertical integration.

> **"I am concerned that Novo Nordisk's merger with Catalent will give Novo Nordisk unprecedented visibility into and control over its competitor's production capacity, costs, and business practices, and the ability to preference its own products and obstruct its competitors' use of Catalent to produce GLP-1 drugs."**
>
> **- U.S. Senator Elizabeth Warren (D-MA)**

Other large multi-national pharmaceuticals have also voiced opposition to the deal:

> **"Limiting the competition in this space is not a good idea…In general, if companies start buying up CMOs, that will limit the amount of competition that there can be…"**
>
> **- Roche CEO Thomas Schinecker**

The FTC issued a "second request" to Novo and Catalent in May 2024. On December 6, 2024, the European Commission officially approved the acquisition of Catalent by Novo Holdings, thus paving the way for the transaction to close (Novo Holdings, #17).

WHAT'S NEXT FOR VERTICAL INTEGRATION?

The successful closing of this transaction could have a wide range of implications on vertical integration across the industry. As critics have noted, Novo Nordisk potentially gaining direct access to Catalent's capabilities could further boost its competitive advantage over the rest of the market: competitors partnering with Catalent could experience possible impacts to pricing, production quality, and service levels correlated with Novo actions; alternatively, competitors seeking another CMO partner may be subject to fewer partner options and therefore increased manufacturing costs and barriers to entry. Life sciences companies could also increasingly consider vertical integration opportunities as feasible pathways towards value creation. Compounded with efficiency-inducing advancements such as the rise of AI enablement to help streamline development, commercial, and backoffice operations, biopharmaceutical companies could potentially pivot core strategy from long term innovation and revenue growth to margin optimization. If deal valuations for novel therapeutics continue to be priced at relative premiums, companies may perceive a potential acquisition of a company engaged elsewhere in the value chain to yield more favourable returns on invested capital (ROIC), particularly if contributing towards a longer-term competitive advantage.

The healthcare industry has already been shaped in recent years through vertical integration across insurers, hospitals and pharmacy benefit managers (PBMs): according to the FTC, 79 percent of prescriptions written in 2023 were driven by the "Big 3" PBMs: CVS Caremark (subsidiary of Aetna), Express Scripts (subsidiary of Cigna) and Optum Rx (subsidiary of UnitedHealth) (Pharmacy Benefit Managers, #12). Though antitrust scrutiny may persist, we generally expect that under new leadership, the FTC's efforts to prioritize fairness for customers alongside competitive balance for businesses may evolve with future policy likely to gravitate towards a less complex dealmaking environment. With the Novo-Catalent deal potentially setting another market-altering precedent across the industry, life sciences companies should strive to incorporate vertical integration considerations into M&A strategy heading into 2025.

THE BIOSECURE ACT AND IMPACT ON DEALMAKING

Originally passed by the U.S. House of Representatives in September 2024, the Biosecure Act aims to prohibit executive agencies from contracting with any entity where the biotechnology equipment or services of a "biotechnology company of concern" would be used in the performance of that contract (H.R.8333, #9). The legislation defines a "biotechnology company of concern" as a biotechnology company that is headquartered in or subject to the jurisdiction of a foreign adversary's government and poses a threat to national security. The bill explicitly names the following five companies that are purported to have "direct ties" to the Chinese Communist Party: WuXi Apptec, MGI, BGI, Complete Genomics and WuXi Biologics.

With the rise in drug developers utilizing outsourced pharmaceutical operations providers such as CDMOs and CROs, the Biosecure Act would cause complexities for life sciences companies utilizing a Chinese CRO or CDMO. One notable example is Cabaletta Bio, a clinical stage biotechnology company pursuing discovery and development of T-cell therapies for autoimmune disease. Cabaletta currently maintains a manufacturing and collaboration agreement with WuXi AppTec for Phase I/II clinical trials of CABA-201, DSG3-CAART and MuSK-CAART, and the company projects that clinical trial progress could likely be impacted because of the Biosecure Act.

> **"If the University of Pennsylvania or WuXi's manufacturing capacity is reduced or otherwise delayed or limited, including due to legislative action, this could adversely impact enrollment in our trials…"**
>
> **- Cabaletta Bio 2023 Annual Report**

With Chinese manufacturers removed from the supply chain, onshore manufacturing and research could become more expensive as fewer options would be available, particularly for smaller biotechnology companies lacking the financial resources of a larger, established biopharmaceutical company. Market imbalance could be further compounded following potential vertical integration deals involving drugmakers and CDMOs similar to Novo Holdings and Catalent. This would have the potential to fundamentally alter the biotech VC and M&A dealmaking environment, as VC firms and acquirers could be in a greater position of leverage given their access to capital, which would be a baseline necessity for biotechs to ensure continued development progress and, ultimately, survival.

One potential alternative for biotechs could be to utilize CDMO and CRO partners in lower-cost jurisdictions such as Mexico and India. India could be positioned as the largest beneficiary from the Biosecure Act. According to the Indian government's Department of Pharmaceuticals 2023 annual report, India "has the highest number of USFDA compliant pharma plants outside of the U.S.," with "500 API manufacturers contributing to about 8 percent of the global API industry," and has market prominence as a small-molecule manufacturing jurisdiction (Annual Report - 2023-24,#2). However, life sciences companies will need to consider several items before choosing to partner with an India- or Mexico-based CDMO or CRO partner, including — but not limited to — evaluating partner capabilities for large-molecule drugs, assessing partner risk and quality control and decoupling arrangements with existing Chinese partners where applicable.

As of the time of this report, the bill is undergoing deliberation in the U.S. Senate, with the Senate version omitting the specific reference to WuXi as a company of concern (S. 3558, #18). With its recent exclusion from the latest U.S. defense spending bill, the expectation is to defer further review until 2025 after all incoming members of Congress are sworn in (Text of the House Amendment to the Senate Amendment to H.R. 5009, #19). Though policy analysts generally convey uncertainty on scope and enforcement of the legislation, the Biosecure Act projects to retain bipartisan support due to its focus on national security – making it crucial for life sciences dealmakers to consider the implications of the legislation for future transactions.

For additional insights around the Biosecure Act, we recommend to view the previously-released A&M whitepaper here: https://www.alvarezandmarsal.com/insights/biosecure-act-recharting-map-biopharma-manufacturing (Guyton and Porter, #8)

05
FINAL THOUGHTS AND PREDICTIONS FOR 2025

We anticipate a continued focus by life sciences companies towards innovation in portfolio strategy, and therefore expect M&A deal volume in 2025 to remain robust, with a strong possibility to exceed 2024 volumes. However, we project deal values to remain subdued, as dealmakers may continue to pursue smaller deals. We expect an active VC deal environment for 2025 with a projected uptick in biotech IPOs.

2025 M&A activity may be further shaped by several additional market forces including:

SPUR ACTIVITY

Activist Investors:

in efforts to recapture enterprise value, pharmaceutical companies may seek to refocus portfolio strategy and divest non-core product assets especially if confronted with activist investment. As a notable example, activist hedge fund Starboard Value acquired a $1.0 billion equity stake in Pfizer on October 6, 2024 (Thomas, #15). Starboard asserts that Pfizer has "invested nearly $70 billion in M&A since the pandemic," yet company results indicate underperformance in the market relative to peers (2024 Active-Passive Investor, #1). Pfizer is reportedly considering a sale of its hospital drugs unit — Pfizer Hospital —previously acquired in 2015 as part of the Hospira transaction, and may possibly look to divest additional non-core assets over time (Sen, #14).

Direct-to-Consumer (DTC) Commercial Models:

In response to increased demand for personalized therapeutics, flexible pricing, and tailored patient journey support, investors could pursue biopharmaceutical companies offering DTC programs that provide a streamlined, cost-effective platform for patients to receive medications and obtain care. Notable examples across large pharma include Pfizer launching PfizerForAll in August 2024 (Pfizer Inc., #19) and Lilly launching LillyDirect in January 2024 (Eli Lilly and Company, #20), joining a market featuring prominent VC-backed companies such as Ro and Hims & Hers.

Breakthrough Technologies:

Continued advancement in technologies such as in-vivo CGT are expected to cultivate strong investor interest. In-vivo mechanisms offer potential to improve scalability, accessibility, and convenience for patients while carrying reduced manufacturing needs relative to other CGT technologies. Despite generally prolonged development timelines and long-term costs, approximately 4.3B USD in total M&A and VC deal value from 2024 originated from notable in-vivo CGT related transactions, with momentum expected to continue through 2025.

MODERATE ACTIVITY

U.S. Public Policy:

With the incoming U.S. presidential administration, most public policy analysts and economists generally project a rollback of antitrust regulations to ease future dealmaking. However, the outlook on drug pricing policies and cross-border trade remains uncertain. Drug affordability and national security currently garner bi-partisan support and therefore, potential rollbacks to IRA or Biosecure Act legislation could face challenges.

Supply Chain Concentration:

A heightened pursuit of innovation will need to be counterbalanced with available manufacturing and supply chain capabilities to guide product launch. Persistent manufacturing challenges within CGT and other novel therapeutic areas combined with a potential decrease in CDMO partner options stemming from vertical integration or the Biosecure Act could create downward pressure on M&A deal valuations, as pathways to launch could become challenging without access to the proper internal or external manufacturing capabilities.

CONCLUSION

As 2025 approaches, deal outlook on the surface for life sciences companies appears mixed: while the continued rise of AI and market demand for Obesity therapeutics have contributed to interest in inorganic growth, high interest rates and geopolitical uncertainty may induce tempered expectations.

Navigating through challenges will require companies to adopt a proactive approach and consider the following:

Continuously review portfolio strategy and remain agile towards implementing key actions (e.g. acquire, divest, prune) in tune with market conditions to optimize value

Explore creative M&A (e.g. earnout structures, partnerships with VC firms) or non-M&A avenues (e.g. R&D collaborations) to drive value accretion

Employ a disciplined, coordinated approach towards integrations and separations to mitigate deal risk

Executives must think boldly beyond the traditional M&A playbook and view uncertainty not as a barrier, but as a catalyst for sophisticated, intentional action.

06
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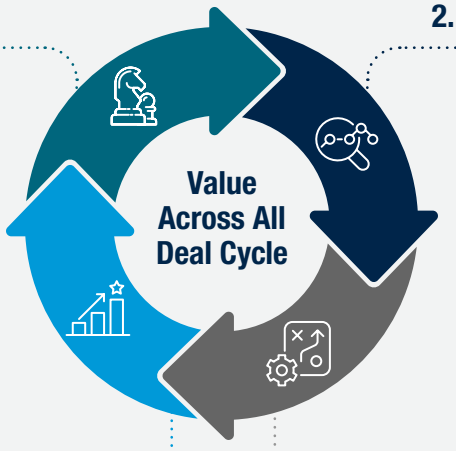

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AUTHORS & CONTRIBUTORS

CORPORATE TRANSACTIONS GROUP LEADER

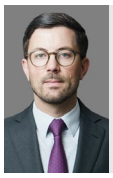
PRESTON PARKER
MANAGING DIRECTOR
pparker@alvarezandmarsal.com

LIFE SCIENCES INDUSTRY GROUP LEADER

MARK FREITAS
MANAGING DIRECTOR
mfreitas@alvarezandmarsal.com

AUTHORS

MARCOS CORTES, M.SC.
MANAGING DIRECTOR, CORPORATE TRANSACTIONS GROUP
marcos.cortes@alvarezandmarsal.com



SIMON JOYEUX
MANAGING DIRECTOR, GLOBAL TRANSACTION ADVISORY GROUP
sjoyeux@alvarezandmarsal.com

ANAND SESHADRI
SENIOR DIRECTOR, CORPORATE TRANSACTIONS GROUP
aseshadri@alvarezandmarsal.com

SEAN HELMIG
SENIOR DIRECTOR, GLOBAL TRANSACTION ADVISORY GROUP
shelmig@alvarezandmarsal.com

CONTRIBUTORS

LYNA SUN
MANAGING DIRECTOR, CORPORATE TRANSACTIONS GROUP
lsun@alvarezandmarsal.com

JAMES GUYTON
MANAGING DIRECTOR, LIFE SCIENCES INDUSTRY GROUP
jguyton@alvarezandmarsal.com

DAVID MÜLLER-ELMAU
MANAGING DIRECTOR, CORPORATE TRANSFORMATION SERVICES
dmueller-elmau@alvarezandmarsal.com

DAARON DOHLER
SENIOR DIRECTOR, LIFE SCIENCES INDUSTRY GROUP
ddohler@alvarezandmarsal.com

MARILYN ADAN
SENIOR DIRECTOR, CORPORATE TRANSACTIONS GROUP
madan@alvarezandmarsal.com

MARWAN RAMADAN
DIRECTOR, CORPORATE TRANSACTIONS GROUP
mramadan@alvarezandmarsal.com

AMIT MALIK
DIRECTOR, GLOBAL CAPABILITY CENTER
amit.malik@alvarezandmarsal.com

KISHAN PATEL
SENIOR ASSOCIATE, CORPORATE TRANSACTIONS GROUP
kishan.patel@alvarezandmarsal.com

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