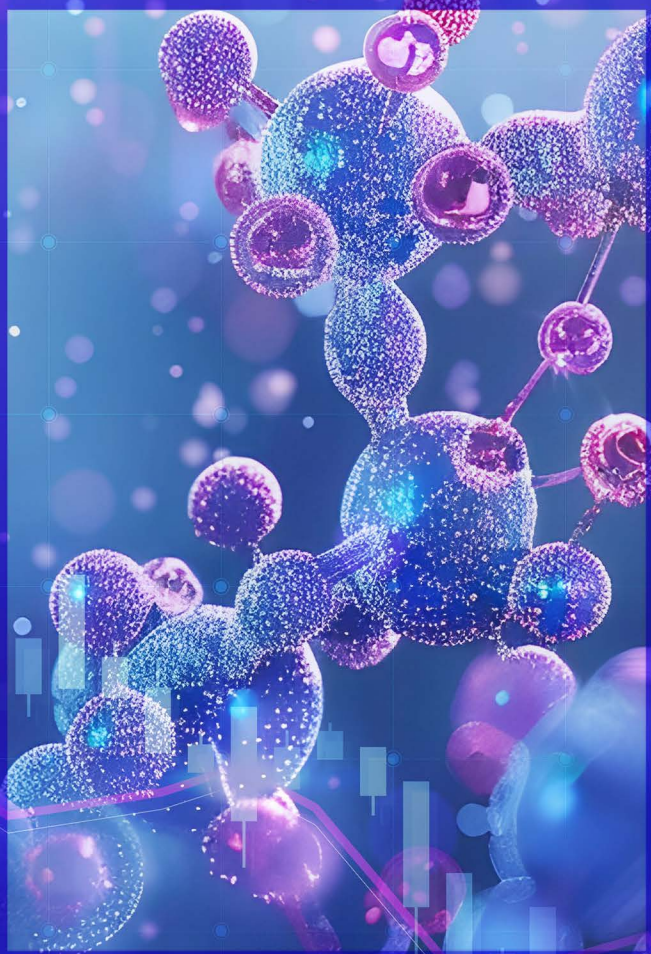
KPMG

Biopharma deal strategy outlook

Will 2024 finish strong?



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KPMG summary insights on trends impacting the biopharma deal landscape

We see several trends converging to impact deal activity over the next five years:

Challenges:

- By 2030, 190 drugs lose patent exclusivity, and 69 of those drugs are blockbusters, which puts $59 billion of industry sales at risk by 2029.[1]

- The Department of Health and Human Services (HHS) under the Inflation Reduction Act (IRA) has reported the first negotiated price discounts on top "blockbuster" drugs (i.e., those with $1 billion or more in revenue), and the price reductions starting in 2026 are significant. The IRA is leading to significant revenue reductions for the pharmaceutical industry. Charles River's recently published white paper predicts that total lost revenue for the pharmaceutical industry could reach more than $968 billion.[2]

- The Federal Trade Commission (FTC) is challenging 300 "junk" patents, many of which are associated with top blockbuster drugs.[3] This may create more immediate generic competition, which would force innovative pharmaceutical players to look for new sources of revenue sooner.

- A period of extended higher interest rates translates to a higher cost of executing deals. While a possible interest rate cut by the Federal Reserve would be positive, the market is still a long way away from the low-interest-rate market that enabled funding of early stage biotechs and enabled innovation to flourish. While modest interest rate pullbacks might help larger companies find viable investment cases for future deals, until there is a larger drop, the innovation to fuel the next generation of young biotechs for deal activity will likely remain less active.

- The global pharmaceutical pipeline's growth rate appears to be slowing to low single digits. The landscape of active available drugs for doing deals is likely getting tighter.

- The FTC will likely continue to focus on the biopharmaceutical industry and look to prevent deals it believes either further maintain a monopoly (see Sanofi-Maze) or believe may cause price increases and harm access for patients.

Opportunities:

- Interest rates appear set to drop, leading to a lower cost of capital. This will enable larger entities to pursue a slightly wider range of deals.

- The focus on the next advanced therapeutics and precision medicine continues to be an important theme across the pharmaceutical industry. However, unlike 2023 when advanced therapeutics made up more than 30 percent of deals, in the first six months of 2024 we have seen a pullback to a place where only 19 percent of deals have been focused in this area.

[1] "FTC targets 300 Big Pharma 'junk patents,' sends warning letters to top drugmakers," benefitspro.com, May 15, 2024

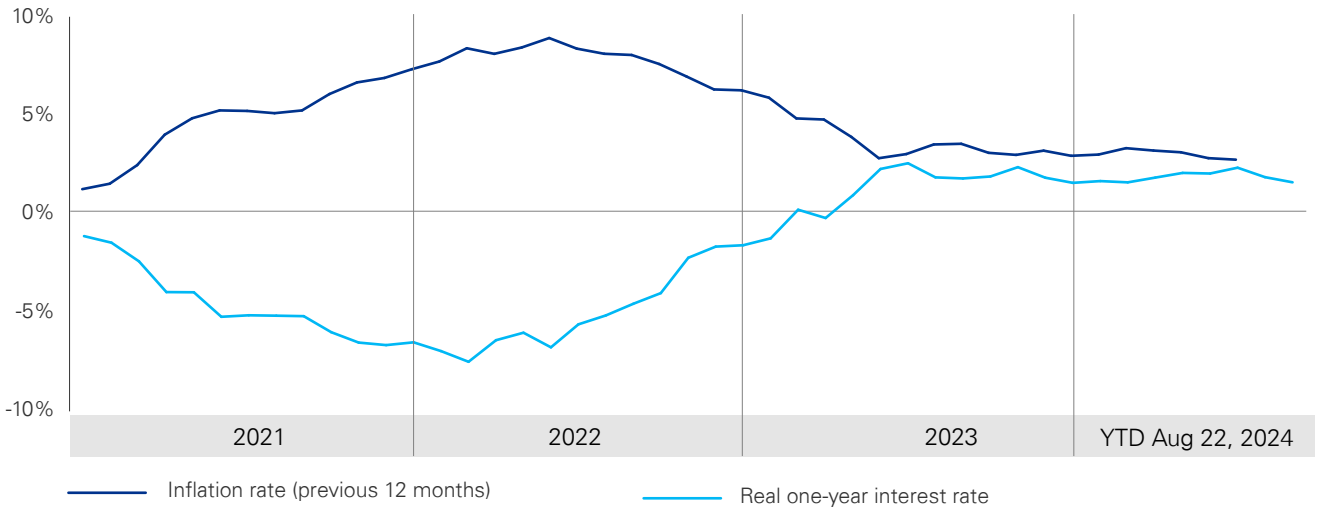
[2] "Implications of the Inflation Reduction Act for cancer medicine development," Charles River Associates, September, 2024

[3] "What are 'junk' drug patents? The FTC is challenging them," qz.com, May 8, 2024

Despite headwinds, the urgency for building pipelines has arrived

The biopharma industry saw exceptional levels of deal activity when interest rates were at historically low rates in 2020 and 2021. Over the last two years, we have seen a pullback to more traditional deal volume levels as interest rates rose (Exhibit 1 and Exhibit 2). Interestingly, toward the end of 2023 and in January 2024, the enthusiasm for executing deals returned despite continued high interest rates. Our data shows the deal activity for the first three quarters of 2023 was on pace to be 100 deals lower than we saw in 2022, but in the fourth quarter, deal activity increased to the point where 2023 ended up just 44 deals lower than in 2022. Further, the number of corporate acquisitions increased significantly in the fourth quarter of 2023, with the full year ending at 114, higher than both 2022 and 2023. The total capital deployed for corporate acquisitions in 2023 (if we exclude one-off mega-mergers over $30 billion) revealed the most capital deployed toward acquisitions across the industry since we started tracking this data in 2017 at $109.5 billion (Exhibit 4). If we include the capital deployed by mega-mergers, the only year since 2017 that outpaced 2023 in terms of total capital deployed was 2019, which included the landmark BMS-Celgene and AbbVie-Allergan deals. Clearly, urgency to build portfolios hit the industry at the end of 2023, despite high interest rates.

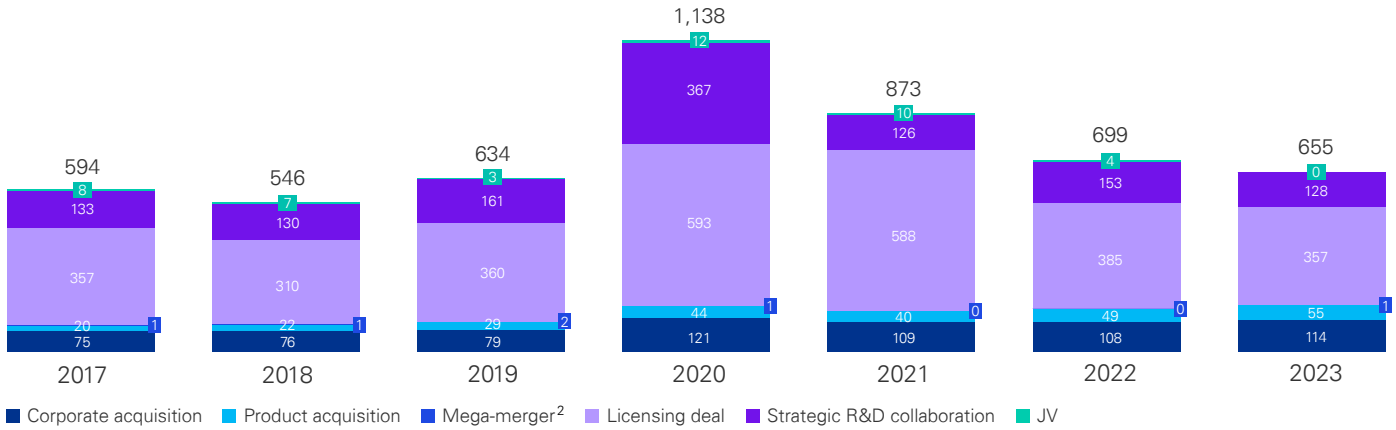
Exhibit 1: Real interest rates versus inflation



The chart above displays the nominal interest rate of a one-year US Treasury bond, the US inflation rate, and the resulting one-year real interest rate. Inflation is defined as the yearly percentage change of the Consumer Price Index (CPI). When inflation is high, prices for goods and services rise, and thus the purchasing power per unit of currency decreases. The chart shows that, adjusted for inflation, the yields on US Treasuries (blue line) have often been negative.

Source: Longtermtrends.net

Exhibit 2: Volume of biopharma deals by deal strategy (2017–2023)



Note(s): 1. Deal count only includes deals where one pharmaceutical executes a deal with another pharmaceutical company. Equity investor deals and debt financing deals have been excluded; 2. Acquisitions >$30 billion

Source(s): KPMG analysis; Data from Informa Intelligence

Exhibit 3: First three quarters biopharma deal volume by deal strategy

Data covering January to September to compare 2021, 2022, 2023

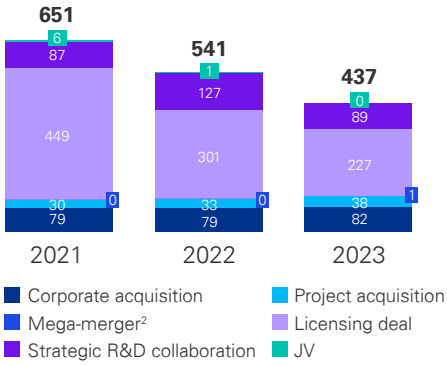


Exhibit 4: Volume of corporate acquisitions versus total M&A value by year (2017–2023)

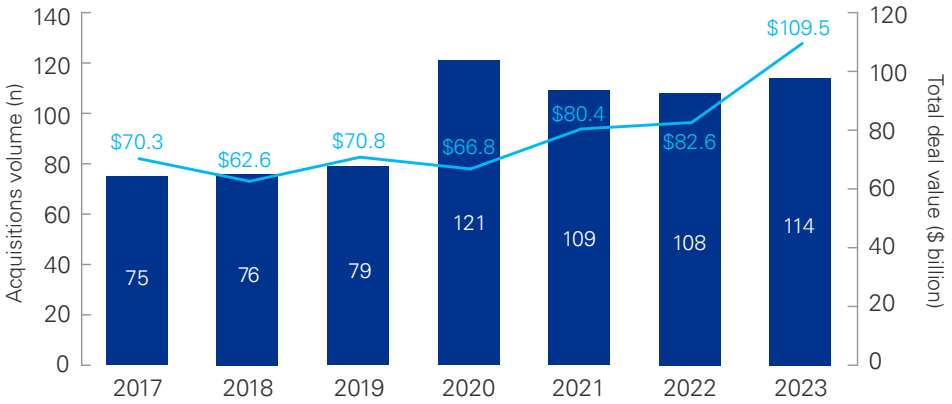


Exhibit 3 Note(s):
1. Deal count only includes deals where one pharmaceutical company executes a deal with another pharmaceutical company. Equity investor deals and debt financing deals have been excluded; 2. Mega-mergers are defined as acquisitions >$30 billion.

Source(s): KPMG analysis; Data from Informa Intelligence

Exhibit 4 Note(s):

1. Mega mergers (i.e., >$30 billion) were excluded due to their outlier effect on year-to-year deal value; 2. Total deal value is incomplete due to the nondisclosure of the total consideration paid by the acquiring/investing entity for a number of deals.

Source(s): KPMG analysis; Data from Informa Intelligence

As we look at the various headwinds and tailwinds facing the pharmaceutical industry, it becomes apparent that the need to do more deals in order to build pipeline portfolios and secure future revenue growth is significant. Several of these headwinds could impact future top 50 pharma revenues, including a large number of patent cliffs between now and 2030 and IRA price reductions (Exhibit 5). While interest rate relief may help deal activity return, uncertainty about how government policies may shift under a new Federal government administration in 2025 may lead to more conservative deal behavior in the short term.

Exhibit 5: Impact of potential headwinds on future pharma revenues

Industry trend	Commentary	Impact on deal activity
Multiple patent cliffs[1,2]	• 190 drugs lose patent exclusivity by 2030 • 69 of those drugs are blockbusters (i.e., $1 billion or more in revenue) • $59 billion of industry sales at risk by 2029 • Represents 46 percent revenue declines for the top 10 largest pharmaceutical companies	⌃⌃
Interest rate relief[3]	• Sept 18, 2024, the Fed cut interest rates by 0.5 percent • Fed chair Powell has indicated more small interest rate cuts are likely in the future	⌃⌃
Election uncertainty	• Uncertainty over whether a Republican- or Democrat-led government will prevail and the implications for what direction policy changes may unfold depending on post-election majority government party priorities	⌄⌄
Policies with bearish implications	• Official implementation of the IRA, which will negatively impact revenues of blockbuster drugs, starting in 2026 (38 percent to 79 percent price discounts)[4] • FTC implementing more aggressive anti-competition and consumer harm prevention policies creating a headwind for a wider range of deals	⌄⌄
Venture funding uncertainty[5,6]	• 2023 VC funding for biotech startups was in the ballpark of $23 billion across 613 deals, a dip of 21 percent from 2022 and 42 percent from the peak in 2021 • Funding rounds in 2024 have been larger on average compared to prior years, but there have been far fewer companies invested in compared to prior years • While larger funding rounds may give start-up biotechs more runway, fewer investments means fewer drug targets, which, if this trend sustains, could mean fewer targets for large pharma to pursue	« »

Source(s): KPMG research and analysis; 1. EvaluatePharma 2023; 2. Pharmavoice 2023; 3. "Fed's Powell: US economy solid, gradual interest rate cuts coming," AP News, September 30, 2024; 4. "First IRA Medicare price cuts unveiled," fiercepharma.com, August 15, 2024; 5. "Top 20 biotech startups raise $2.9B in Q1 2024 funding surge," drugdiscoverytrends.com, April 5, 2024; 6. "Biotech financing: darkest before the dawn," Nature Biotechnology, August 8, 2023

Another significant threat to revenue the pharmaceutical industry is facing is the number of loss of exclusivity (LOE) events, many of which are top blockbuster therapies of many of the largest pharmaceutical companies. By 2029, the industry is facing $59 billion sales at risk among the top 10 largest pharmaceutical companies.[4] In total, 190 drugs will lose patent exclusivity by 2030, and 69 of them are blockbuster drugs that several major pharmaceutical companies depend on.[5] In total, the industry is facing a loss of $200 billion in revenues by 2030.

In addition to the industry facing numerous patent threats, there are two other significant threats to future revenues the industry may need to navigate. HHS announced the first drug price negotiations under the IRA in August. The range of drug price discounts are varied and very steep. Each of these products is key to the portfolio performance of their respective companies and will likely create growth challenges for them.[6] Unless there is a legislative change, up to 60 top-selling drugs will be impacted by 2029.[7] If proposed policies to expand the number of drugs negotiated per year occur, the overall impact of the IRA will become more industry wide, and create greater performance pressure.

The other significant threat facing the industry is the FTC's announcement that it is pursuing what it termed as "junk patents."[8] The FTC is arguing that multiple companies across the pharmaceutical industry are filing bogus patent listings to block generic competition, thus inflating the cost of prescription drugs. The first legal cases on this initiative have not yet been adjudicated. However, the outcome may lead to shortened patent protections for many leading drugs.[9] The FTC has stated it is targeting more than 300 different Organ Book patent listings they consider "junk," with the stated goal of invalidating these patents to shorten the patent protection time of many branded drugs,[10] thus lowering cost.

[4] "How steep is pharma's patent cliff?," PharmaVoice, June 14, 2023

[5] "Fortifying Defenses Pre-Patent Cliff," pharmexec.com, September 8, 2023

[6] "Medicare Drug Price Negotiation Program: Understanding Development and Trends in Utilization and Spending for the Selected Drugs," hhs.gov, December 14, 2023

[7] "Impact of the Inflation Reduction Act on biopharma portfolio strategies," kpmg.com, 2023

[8] "What are 'junk' drug patents? The FTC is challenging them," qz.com, May 8, 2024

[9] Ibid.

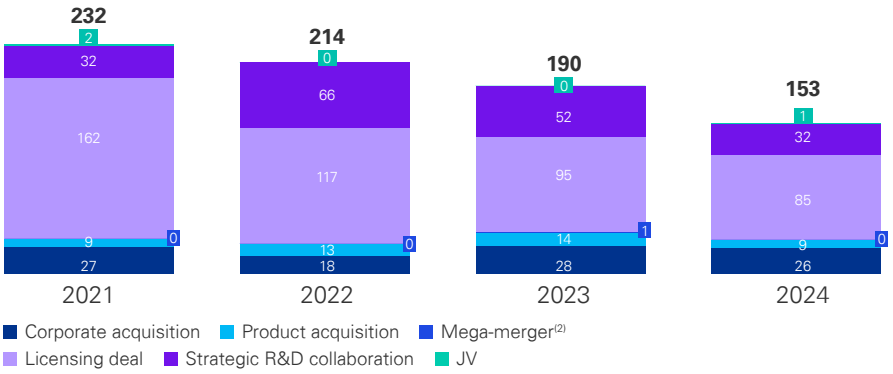
[10] "FTC expands patent listing challenges, targeting more than 300 junk listings for diabetes, weight loss, asthma and COPD drugs," ftc.gov, April 30, 2024

> By filing bogus patent listings, pharma companies block competition and inflate the cost of prescription drugs, forcing Americans to pay sky-high prices for medicines they rely on.
>
> — FTC Chair Lina M. Khan[11]

All of these challenges facing the pharmaceutical industry will have differing degrees of impact on each company's revenue outlook for the next five to six years. It may force some companies to accelerate the timing of when they need their next generation of pipeline drugs to replace lost growth. As discussed earlier, we saw evidence that the realization of these looming threats necessitated more portfolio development activity during 4Q 2023, when multiple pharmaceutical competitors made one or more acquisitions in December, and then into January 2024. More specifically, approximately 33 percent of the deal volume in 2023 was completed in the fourth quarter, whereas in the prior two years a quarter or less of the deal volume occurred in the fourth quarter (2022 with 22.6 percent and 2023 with 25.4 percent).[12] This is a significant swing considering 2022 was still one of the highest deal volume years since 2017.

The deal enthusiasm[13] we saw right before and during the JP Morgan Healthcare Conference in January appears to have waned in 2024. While corporate acquisitions remain healthy and in line with 2023, overall deal volume was significantly lower (Exhibit 6) during the first quarter. There was a significant contraction of licensing deal strategies and strategic R&D collaborations during the first quarter of 2024. But after adding in second quarter deal performance (Exhibit 7), it becomes clear that as the Fed discussion of interest rate cuts materialized, the pharmaceutical deal market began to bounce back. Specifically, the data shows deal volume returned for the first six months of 2024 in licensing deals, while product acquisitions and strategic R&D collaborations gained ground versus the same period in 2023.

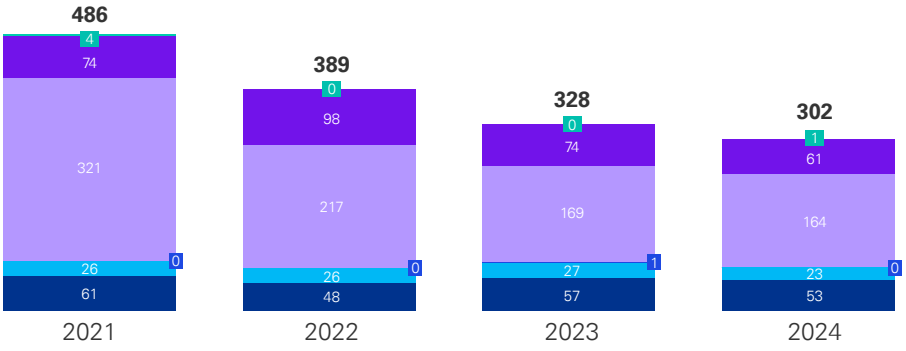
Exhibit 6: 2024 Q1 deal volume by deal strategy
Data covering January to March to compare 2021–2024



Note(s): 1. Deal count only includes deals where one pharmaceutical company executes a deal with another pharmaceutical company. Equity investor deals and debt financing deals have been excluded; 2. Mega-mergers are defined as acquisitions >$30 billion.

Source(s): KPMG analysis; Data from Informa Intelligence

Exhibit 7: 2024 first six months of deal volume by deal strategy
Data covering January to June to compare 2021–2024



Note(s): 1. Deal count only includes deals where one pharmaceutical company executes a deal with another pharmaceutical company. Equity investor deals and debt financing deals have been excluded; 2. Mega-mergers are defined as acquisitions >$30 billion.

Source(s): KPMG analysis; Data from Informa Intelligence

[11] "FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs," ftc.gov, April 30, 2024

[12] KPMG analysis

[13] KPMG analysis

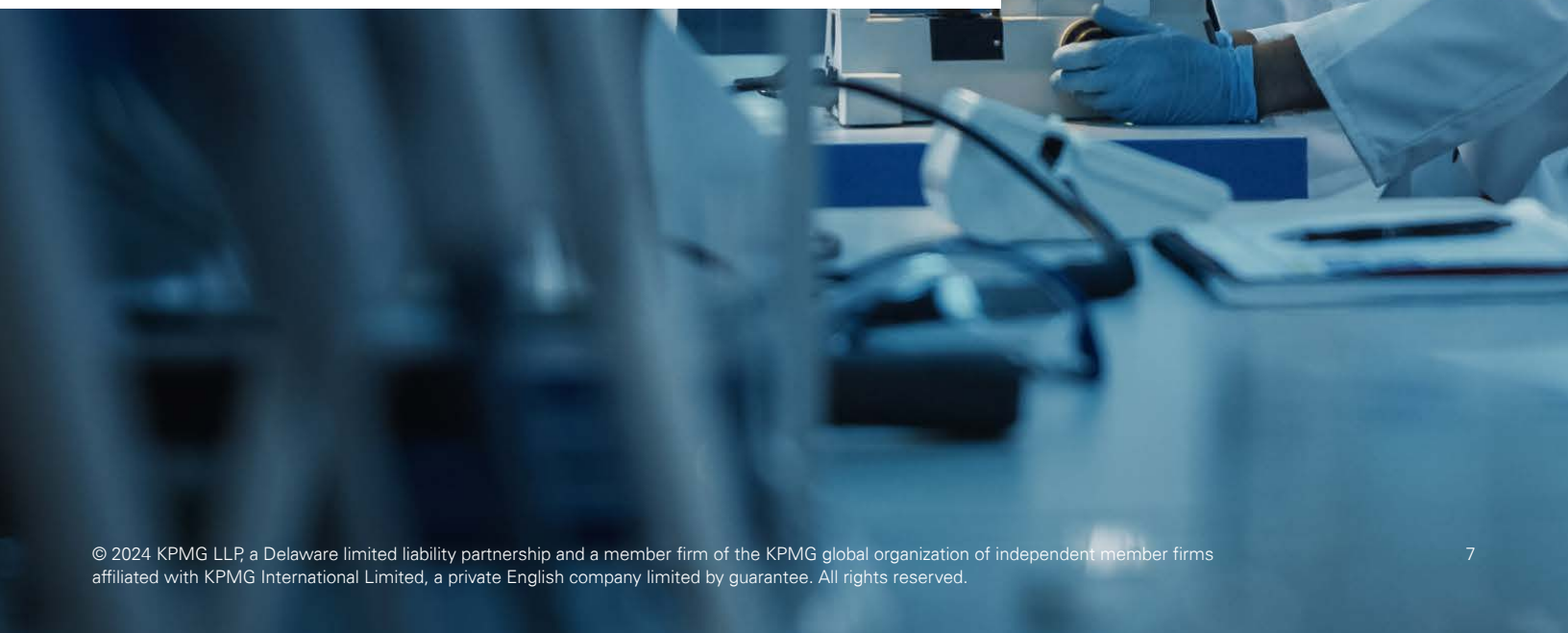
A range of other uncertainties is likely to impact deal flow. On the one hand, the anticipated decline of interest rates many analysts were predicting to occur earlier in 2024 has not come to fruition.[14] While the market seems to be expecting a rate cut in September 2024, a host of potential policy changes remain on the horizon. This includes the Biden administration's public comment about amending the number of drugs that could be negotiated under the IRA for Medicare from 20 per year to 50.[15] When you combine the proposed change to the IRA on top of the recently announced price discounts set to deploy in 2026, the impact for the industry at large could be dramatic. In August, the first 10 drug pricing discounts were announced, and the discounts ranged from 38 percent to as high as 79 percent. The majority of price discounts were north of 60 percent[16] If this degree of pricing impact were spread across even more drugs, the impact would become more industry-wide versus an event for a select few companies. That change would dramatically alter the urgency for deals and the need to accelerate drugs in development for the pharmaceutical industry.

Almost in parallel with the implementation of the IRA, the FTC continues to maintain its stance on higher scrutiny on pharmaceutical deals and taking a broader view on what it considers to be anticompetitive. In sum, the current state for doing pharmaceutical deals is more challenging: the cost of executing deals is more expensive (i.e., higher interest rates); the lifetime of a drug's value is potentially different than it was prior to 2023 (i.e., IRA price negotiations); and the ease of building portfolios and pipelines to help mitigate future revenue cliffs is now harder and slower due to policy around deals (i.e., the FTC's new approach to deal analysis and anticompetition). Overall, these elements are making it tougher for pharmaceutical companies to find their next generation of assets necessary to sustain growth and weather patent expiration. But, as we also highlighted, the need to build pipeline portfolios remains significant given the likely future challenges to growth, and it will likely just be harder to do so than in previous years. All of this suggests, whether portfolio development is organic or inorganic, the need for pipeline innovation continues to be significant.

[14] "Fed holds rates steady, indicates three cuts coming in 2024," cnbc.com, December 14, 2023

[15] "Biden proposes strengthening Medicare's drug pricing power," biopharmadive.com, March 7, 2024

[16] "IRA negotiations slash Medicare prices for Big Pharma blockbusters by up to 79%," Fierce Pharma, August 15, 2024

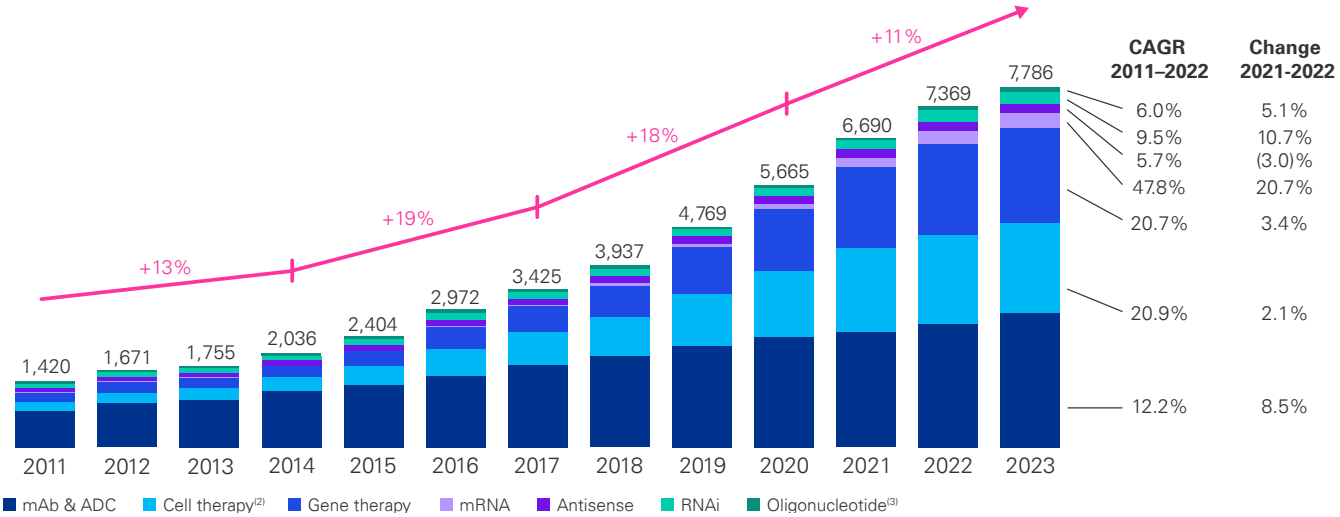


Is global pipeline innovation accelerating or has it slowed?

Understanding that a major proportion of deals in the pharmaceutical industry are focused on precommercial assets, tracking the relative strength of innovation is key for understanding any risks associated with the external supply of innovative assets for larger pharmaceutical companies to add to their portfolios. For the last decade, we have seen strong growth of pipeline innovation across the pharmaceutical industry. The global pipeline continues to expand in terms of the number of new drugs per year. Citeline, for example, reported that in 2023 we saw only 93 new drug targets developed, which was down from the typical average of 100 per year.[17] As an example, a downturn in big pharma on direct spend on discovery research was seen in Charles River Laboratories' results for the second quarter of 2024. It reportedly saw demand for its discovery and safety assessment services decline and cut its revenue forecasts to lower single digits of 4.5 percent.[18] These are signs of trouble for future growth if spend on early-stage assets is falling off. All of which made KPMG LLP (KPMG) ask, is there more evidence of trouble on the horizon?

Our own analysis on the advanced therapeutics landscape (i.e., cell, gene, RNA, and other next-generation therapeutic categories) also shows that the global pipeline slowed from a growth rate standpoint (Exhibit 8). Our analysis reveals an overall strong growth rate since 2011. However, if we compare growth rates across multiple 4-year periods (Exhibit 8), the data clearly shows the overall rate across almost every major advanced therapeutic category declined in the past 4 years versus the past 10 years.

Exhibit 8: Worldwide precommercialization biologic pipeline (2011–2023)



Note(s): 1. Includes registered, preregistration, Phase III, Phase II, Phase I, and preclinical assets. Numbers are not additive as assets can be categorized into more than one category; 2. Includes CAR-T, stem cell, T cell receptor, tumor-infiltrating lymphocytes, and other cellular therapies; 3. Non-antisense, non-RNAi

Source(s): KPMG analysis; Data from Informa Intelligence

[17] "2024 Pharma R&D Annual Review," Citeline, May 21, 2024

[18] "Big drugmakers have cut outside R&D spending amid broad pullback, key contractor warns," endpts.com, August 7, 2024

Even more concerning is that the rate of growth from 2020 to 2021 remained at 18 percent, but then shrank to 10 percent from 2021–2022, and then shrank to 6 percent overall from 2022 to 2023. This suggests a significant shift in the number of active pipeline drugs in development in the most innovative areas of pharmaceutical drug development. When we dig into geographic changes of innovation rates and trends, they reveal some interesting observations.

Not surprisingly, the US remains the epicenter for innovation for the pharmaceutical industry,[19] but US pipeline growth has begun to significantly stall compared to other countries across the globe. Historically, the US has averaged a 4.8 percent pipeline growth since 1995.[20] From 2023 to 2024, the US's growth rate stumbled to 3.6 percent and was dwarfed by the overall global rate of active pipeline agents of 7.3 percent.[21] If we look deeper into individual country competitors to the US, their growth rates for the number of active pipeline assets significantly outpaces US growth rates. Notably, China has become the second largest market for active pipeline assets and number of pharmaceutical companies headquartered in their borders. China is currently developing 26.7 percent of the active pipeline drugs, which accounts for a 200.9 percent growth rate since 2019.[22] South Korea has quickly become the third largest contributor to the global pipeline at 14.2 percent, replacing the UK (13.8 percent). If we dig into why and how two Asian countries have so quickly grown their local country asset pipeline, several country-specific policy and investment strategies appear, but it also reveals some significant red flags. For example, in South Korea, government agencies, policy groups, and global pharmaceutical companies implemented a range of strategies that resulted in significant investments in 2019.[23] These strategies were focused on fostering local development of the life sciences industry and enabling acquisitions of foreign pharmaceutical companies.

[19] "2024 Pharma R&D Annual Review," Citeline, May 21, 2024

[20] Ibid.

[21] Ibid.

[22] Ibid.

[23] "Korea's drug pricing policies in 2023," lexology.com, March 17, 2023

The number and range of South Korea's multiyear investments programs is impressive:

1

The Ministry of Science along with other government ministries have a five-year, 42KRW billion incentive program for supporting domestic AI-research teams to develop technologies relevant for life sciences research and clinical trials.[24]

2

Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) has launched a task force to support AI-based new drug development and is establishing a New Drug Development AI Centre.[25]

3

The Korean government plans to invest 10KRW trillion over the next 5 years in collaboration with local pharmaceutical companies to improve biopharma output by 20 percent annually.[26]

4

The Korean government has developed a 500KRW billion fund to help local pharmaceutical companies expand their presence in the global drug market through acquisition of promising drug makers in other countries.[27]

5

South Korea's Ministry of Health and Welfare is strengthening its coverage and reimbursement of innovative drugs and support for innovative drug pricing by expanding its scope of risk-sharing agreements.[28]

[24] "Will AI change the landscape of the pharmaceutical industry in South Korea?" realstaffing.com, January 2019

[25] Ibid.

[26] Ibid.

[27] Ibid.

[28] "Korea's drug pricing policies in 2023," lexology.com, March 17, 2023

Similarly, since 2015, as part of its Made in China 2025 national strategic plan, China has made wide-ranging policy changes and investments both in terms of building out the regulatory infrastructures and incentive programs to entice both local and foreign investments to enable growth in the pharmaceutical industry. These investments have allowed China to transition its life sciences industry from a largely generic market and expand toward a leading geography for innovative pharmaceuticals.[29] The results of this push to become a recognized leader in biopharma have been well documented.[30] The boom of innovation in China has also come with some significant red flags, and these have created some significant headwinds. There are several reports of fraudulent clinical trial results coming out of China. One BMJ article published in 2016 noted that 80 percent of China's clinical trial data are fraudulent.[31] This is an alarming issue for the country producing the second most innovative pipeline drugs in the world. Getting foreign investment in an environment where the integrity of the clinical research is in such question raises a massive buyer-beware issue that China will need to correct through regulatory enforcement, and this is not a reputational issue that can be fixed in just a few years. In fact, US companies and policy makers have started decoupling the US biopharmaceutical industry from China. Numerous companies are looking for new CDMO partnerships, and the Biosecurities Act, if approved, would further restrict US investments in China entities and vice versa.[32]

Despite having some successfully approved FDA and EMA drugs that have originated out of China, the fraudulent clinical trial data issue has other ramifications. Most data analysis on the global pharmaceutical pipeline suggests it is growing at a reasonable rate, but if a significant portion of the assets coming out of China are not viable due to fraud, does that mean the global pharmaceutical pipeline is really growing, stagnant, or declining? For every successful China-originated asset that has received Western regulatory approval (e.g., BeiGene's tislelizumab and RemeGen's disitamab vedotin), a significant percentage of pipeline assets from China has been plagued by fraudulent data. Experts also note that much of China's pharma innovation push has been potentially copying innovation from others or creating "me-too" products.[33] For example, BeiGene's tislelizumab is a PDL-1 inhibitor and was the sixth FDA-approved anti-PD-1 checkpoint inhibitor, 10 years after Merck received approval for Keytruda. So, if a portion of the innovation from China is based upon fraudulent clinical data, and another portion is coming from appropriately developing me-too drugs or illegally copying others' IP, then how much innovation coming out of China can reliably be considered as a part of the global pipeline growth? Also, if there are questions about the veracity of innovation coming out of China, would we see this reflected in deal flow given we have an industry that largely builds pipelines through deals?

When we examine the geographic activity and flow of biotech acquisitions, we see activity is still predominately happening in the US: from 2021 to 2023, there were 236 biotech acquisitions in the US, easily outpacing all other countries (Exhibit 9). While companies headquartered in China had some activity acquiring biotechs from other countries, there was minimal activity of US or Western European countries acquiring Chinese biotechs between 2021 and 2023.

[29] "The impact of China's policies on global biopharmaceutical industry innovation," itif.org, September 8, 2020

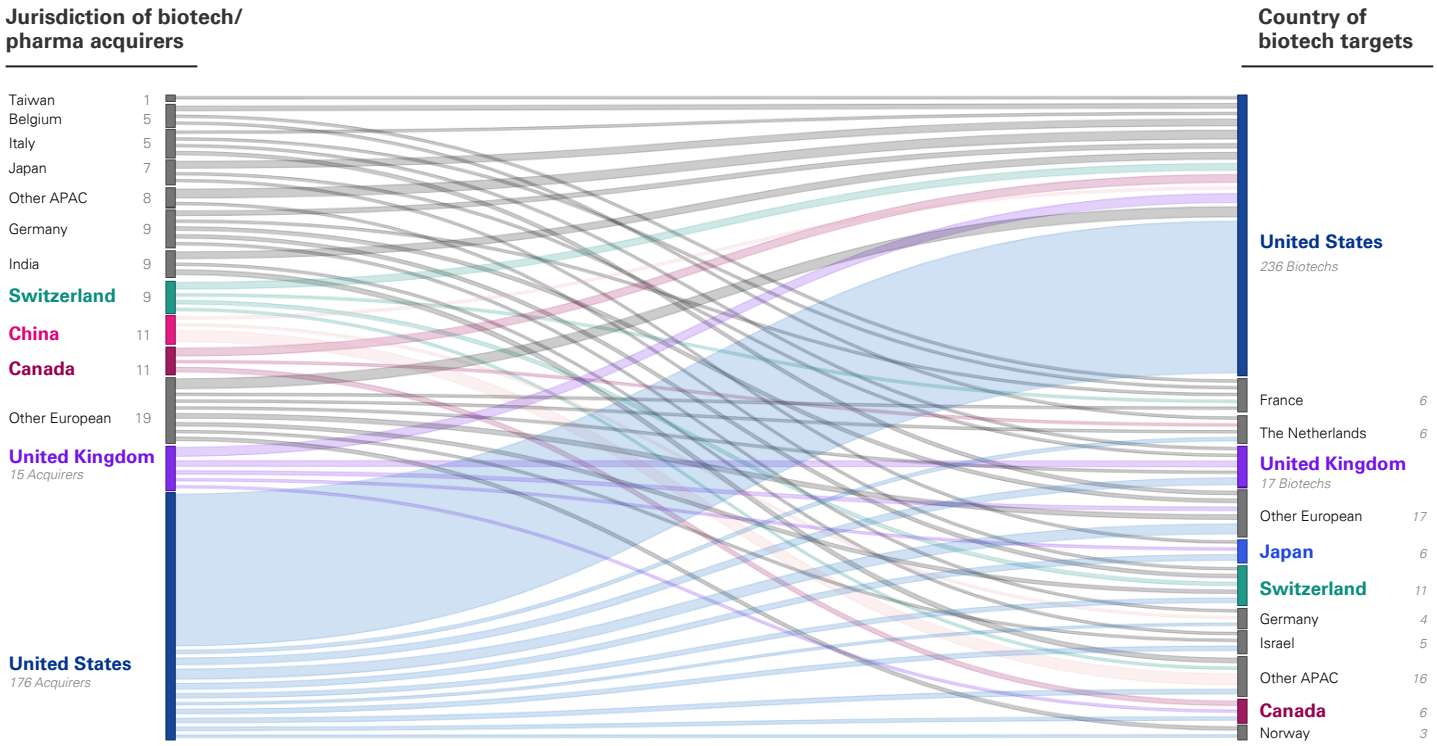
[30] "Vision 2028: How China could impact the global biopharma industry," mckinsey.com, August 2022

[31] "80% of China's clinical trial data are fraudulent, investigation finds," BMJ, October 5, 2016

[32] "House's updated biosecurity bill sets 2032 decoupling deadline for industry's work with WuXi AppTec, WuXi Biologics," Fierce Pharma, May 10, 2024

[33] "Chinese pharma's history of counterfeits, fakes, and quality issues," The China Project, March 16, 2021

Exhibit 9: Global biotech M&A activity (2021–2023)



Sources: KPMG internal analysis; data from Citeline 2024

The lack of deal activity in juxtaposition with the growth of innovative pipeline assets emerging in China suggests Western pharmaceutical buyers have concerns about acquiring Chinese innovation. Future Chinese activity is likely not going to improve as new reports continue to surface suggesting fraud and active non-compliance with FDA regulatory standards. For example, the FDA recently filed a Form 483 against Jiangsu Hengrui Pharmaceuticals (Hengrui) for manufacturing noncompliance including poor contamination controls, subpar cleaning protocols, and failure to promptly hand over documentation to inspectors, which included observations of staff actively destroying and hiding documentation.[34] This comes on the heels of GSK acquiring Aiolos Bio for $1 billion in up-front payment in January 2024. Aiolos Bio had acquired exclusive rights outside of China to AIO-001 from Hengrui. No asset originating from Hengrui can receive FDA approval until these compliance issues are addressed. Events like this justify the FDA's insistence that drugs seeking approval need to complete registration trials that recruit patients from multiple countries and have a significant sample from the US market. Unfortunately, for many Chinese late-stage pipeline drugs, it means they will require additional Phase III studies with high regulatory scrutiny.

On the US front, innovation is also being challenged. The US remains the world's premier hub for pipeline drug origination; however, it is also facing multiple headwinds. Earlier, we discussed signals that big pharma is likely spending less on drug discovery, as seen in the Charles River Laboratory results. Another key headwind to innovation in the US can be seen in the venture capital (VC) landscape. As interest rates remain high, the cost of capital has become dramatically more expensive, which has impacted the behavior of the VC market. While the start of 2024 marked a more active VC market, investments focused on preclinical companies have fallen off, even if the size of private round funding has increased.[35] The funding sources for these early stage biotechs have been further restricted as fewer young biotech companies have been able to go public.[36] High quality clearly matters in the current

[34] "FDA cracks down on China's Hengrui in scathing manufacturing write-up," Fierce Pharma, June 6, 2024

[35] "As biotech recovers, venture firms' preferences appear to shift," biopharmadive.com, June 6, 2024

[36] "Biotech IPOs are the industry's lifeblood. Track how they're performing here," biopharmadive.com, August 26, 2024

IPO market, and investors appear to strongly favor companies that are clinical-stage with well-known industry veteran management teams. This is leaving many of the founder-scientists leading new biotech companies (especially pre-IND and preclinical stage) struggling.

A possible change in behavior by the VC sector might have meant more opportunity for pharmaceutical companies to find attractive deals, but this has not happened due to another important headwind facing the deal market. The FTC's more assertive policies and broader definitions on what it considers anticompetitive and monopolistic is making deals more difficult. Since 2021, KPMG has been following the Lina Khan-led FTC,[37, 38, 39] and we believe the case the agency brought against Sanofi for the Maze Therapeutics deal should be instructive for the industry. The FTC's position was that because Sanofi is currently the only manufacturer with a commercialized therapeutic for Pompe Disease, this made its acquisition of Maze's Phase I asset MZE001 a monopolistic deal. The FTC stipulated that such a deal would likely only hurt patients in the future by giving Sanofi more ongoing pricing power. There are currently 34 drugs in development for Pompe disease, and many are being developed by other large pharmaceutical competitors of Sanofi (e.g., Astellas, Roche, and Bayer via Askbio to name a few). Several of the drugs in development for Pompe disease are in Phase II (e.g., Roche's gene therapy). Given the numerous major competitors investing in Pompe disease, it seems the future of the Pompe disease market was shaping up to be highly competitive. It is notable that the FTC did not appear to consider Maze's product was not going to be curative for Pompe disease, while the gene therapies in development (and in later stages) have the potential to be. The FTC's stance on Sanofi in the deal may be penalizing Sanofi for bringing the first therapy to market for Pompe disease, and attempting to prevent Sanofi from taking advantage of the significant infrastructure and experience it has developed serving this population. This policy stance may be in direct opposition to other policies the US has in place to foster innovation, such as offering market protection for pharmaceutical companies that take the risk to invest billions in hopes of bringing a new drug to market that address unmet needs. It appears the FTC clearly believes pursuing deals involving early stage biotechs is the right policy direction.

> "The [Sanofi-Maze] complaint also broke new ground by charging that an acquisition of a product in the pipeline with no sales can still constitute illegal monopolization... The postcomplaint abandonment of Sanofi's deal with Maze marks another successful effort by the Commission to protect competition in the pharmaceutical industry."
>
> — Lina Khan, from her postdeal abandonment statement[40]

In light of the challenges of pipeline assets coming out of China, as well as the funding and policy restrictions in the US, is the global pipeline growing or stagnant? It is impossible to reliably measure the answer. Given the US and China are responsible for 75.6 percent of the global pharmaceutical pipeline, the global pipeline growth rate is certainly much lower than 7.8 percent and likely much closer to the US growth rate of 3.6 percent. From a deal trends standpoint, a slowing rate of pipeline growth should translate to a certain set of deal behaviors across the market. We should see heightened competition for each deal in a deal landscape most experts already describe as highly competitive. We should also see more deals focused on very early stage assets (i.e., preclinical to Phase I), and competition will likely drive valuations higher. The wildcard in this dynamic is if the FTC's behavior creates an atmosphere where certain large companies avoid pursuing certain targets, which could artificially remove some competition from a bidding process. That may either stagnate or decrease valuations in certain segments of the deal market. In a time for the pharmaceutical industry when funding for early stage innovation has become much more challenging, the impact of US policies and the regulatory challenges in China are clearly adding more challenges to innovation just when the industry seems to be in greater need.

[37] "Biopharmaceuticals deal trends: What to expect in 2021," kpmg.us, 2020

[38] "Biopharma deal trends outlook for 2023: Q3'22 M&A trends in life sciences," kpmg.com, 2023

[39] Ibid.

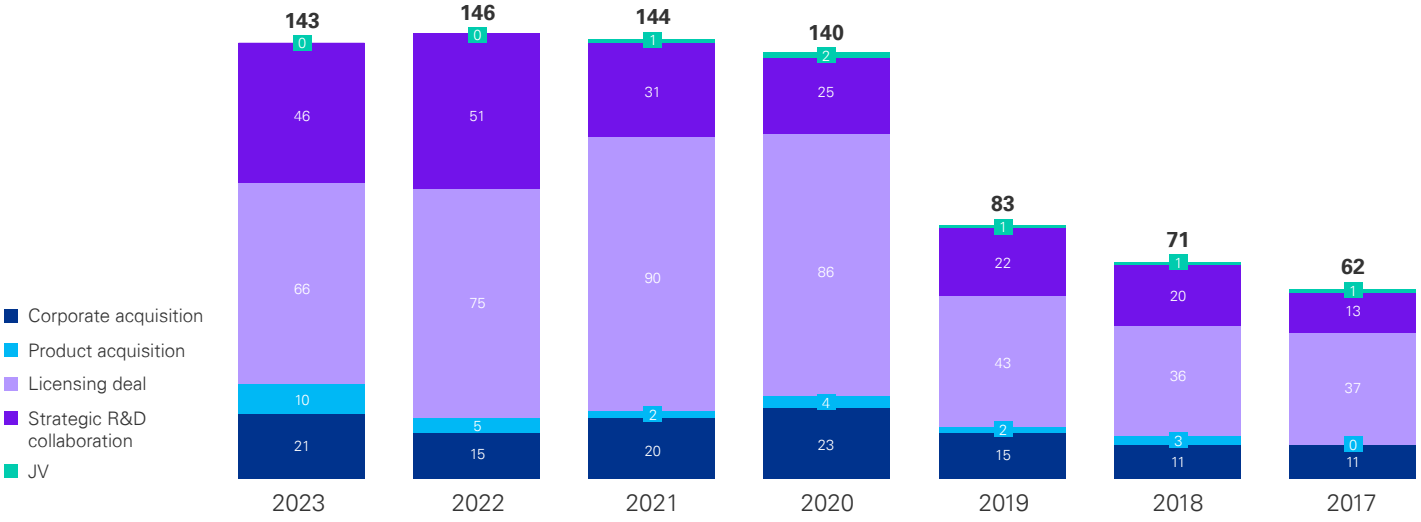
[40] "Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter In the Matter of Sanofi/Maze Therapeutics Commission File No. D09422," ftc.gov, December 20, 2023

Will 2024 deals continue to focus on advanced therapeutics?

For the past four years, the pharmaceutical industry had significantly increased its focus on complex, advanced therapeutics such as cell, gene, and bispecific/multispecific therapeutics (Exhibit 10). In 2023, for example, 22 percent of the total deal volume was focused on just cell and gene therapy modalities, and 9 out of 10 of the largest acquisitions were focused on precision medicine (Exhibit 11). Precision medicine-focused therapies have been a growing trend across the deal landscape. For the first six months of 2024, we have seen a pullback on deals focused on gene therapy and bispecific/multispecific therapeutic classes of drugs; however, cell therapies for the first six months remain on track compared to 2023 (Exhibit 12 and Exhibit 13). Overall, advanced therapeutic deals as a group represented only 19 percent of the total deals for the first six months of 2024, which is significantly less than the 31 percent of deals we saw in 2023. The pullback on gene therapy deals may be due to a number of factors, including:

1. Fewer remaining, nonpartnered or acquired small biotechs within clinic assets
2. Industry concerns about recent clinical trial challenges seen in the gene therapy space
3. The poor commercial performance of recently launched gene therapies.

Exhibit 10: Total volume of cell and gene therapy deals by deal strategy type (2017–2023)



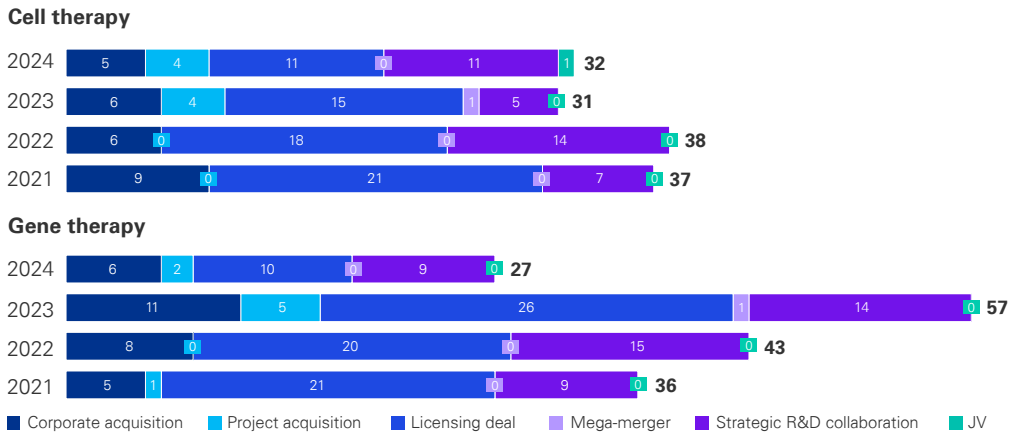
Year	2023	2022	2021	2020	2019	2018	2017
Total deals	655	699	873	1,138	634	546	594
% CGT	22%	21%	16%	12%	13%	13%	10%

Source(s): KPMG analysis; Data from Informa Intelligence

Exhibit 11: 9 of the 10 largest pharmaceutical deals involving precision medicine as a strategy

	Acquirer	Target	Deal month	Deal value	Primary therapy area	Precision medicine component
1	Pfizer	Seagen	March	$43B	Oncology	Seagen has a portfolio of antibody-drug conjugates (ADCs) for various oncology indications.
2	BMS	Karuna	December	$14B	CNS	None
3	Merck	Prometheus	April	$10.8B	Immunology	Prometheus is developing PRA-023 for various autoimmune indications. The asset targets TL1A, and the company is stratifying patients using a CDx.
4	AbbVie	Immunogen	November	$10.1B	Oncology	Similar to Seagen, Immunogen brings AbbVie a portfolio of ADCs.
5	AbbVie	Cerevel	December	$8.7B	CNS	Cerevel is developing a portfolio of CNS assets, using patient stratification based on disease phenotype (e.g., late versus early Parkinson's).
6	Biogen	Reata	July	$7.3B	CNS	Reata focuses on rare disease, including Skyclarys for Friedreich's ataxia.
7	Roche	Telavant	October	$7.1B	Immunology	Similar to Merck/Prometheus, Telavant has an asset targeting TL1A.
8	Astellas	Iveric	April	$5.8B	Opthalmology	Iveric brings Astellas a portfolio of assets for rare retinal eye diseases.
9	BMS	Mirati	October	$4.8B (+ $1B CVR)	Oncology	Mirati has launched Krizati, for lung cancers with G12C mutations.
10	BMS	RayzeBio	December	$4.1B	Oncology	RayzeBio is developing a portfolio of radioligand assets for various cancers.

Exhibit 12: First six months total volume of advanced therapy deals by deal strategy type (2021–2024)

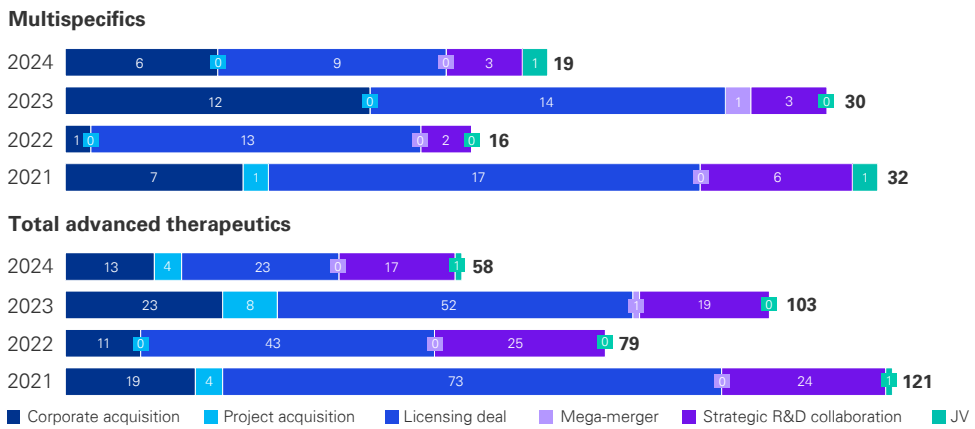


Total deals	% Cell therapy
302	11%
328	9%
389	10%
486	8%

Total deals	% Gene therapy
302	9%
328	9%
389	11%
486	7%

Source(s): KPMG analysis; Data from Informa Intelligence

Exhibit 13: First six months total volume of advanced therapy deals by deal strategy type (2021–2024)



Total deals	% Multispecifics
302	6%
328	9%
389	4%
486	7%

Total deals	% AT
302	19%
328	31%
389	20%
486	25%

Source(s): KPMG analysis; Data from Informa Intelligence

Given overall innovation trends heading toward more targeted therapies, it is unlikely the industry will see a long-term pullback on precision medicine deals. However, with the massive success of therapeutics, including GLP-1s, and the immense size of markets they can serve across a wide range of indications, we may see the industry take a brief run toward me-too assets or related therapies that can be used either as a combination formulation drug-development strategy or as a separate add-on prescription therapy. Areas associated with metabolic health, such as weight loss, cardiovascular prevention, metabolic dysfunction-associated steatohepatitis (MASH), and perhaps even new approaches to Alzheimer's disease, are likely to be on the horizon. The attractiveness of these markets is a throwback to the 1990s and early 2000s when large population therapies that made billions (e.g., Lipitor, Crestor) were the hallmark of the industry. The resurgence of this focus by the pharmaceutical industry in these types of large population markets is just starting.

Deal market predictions

We see several trends occurring in the second half of 2024 and early 2025:

01 We anticipate mega-mergers will continue to largely remain out of favor in the industry. While the impact of the IRA and future LOEs may create some challenges for the industry over the next 5+ years, most large pharma and biotech companies have been diligently building their pipeline portfolios for the past four years. Barring a series of major pipeline performance setbacks, we do not anticipate most pharmaceutical companies will consider this option. Additionally, given the current FTC's focus on implementing more assertive policies, there could be challenges to achieving approval for a synergistic mega-merger.

02 Licensing deals and other creative deal structures will remain popular as larger players need deal mechanisms to mitigate the risks of having to transact for earlier-stage assets.

03 Given the Fed's interest rate cut in September and more possible cuts in early 2025, we anticipate deal volume to continue to grow and keep pace with the volume of deals we saw in 2022 and 2023. The fourth quarter of 2024 should be particularly active, and if additional rate cuts occur, deal momentum should carry into 2025.

04 If Democrats win the presidential election, we anticipate the FTC will continue its new, more-assertive policies on limiting deal activity. If Republicans win, the FTC will likely see a regime change; however, some more assertive policies may remain.

05 Big pharma will not depart from their precision medicine focus, but large population therapeutics will increasingly become a more popular investment strategy, particularly as the industry identifies more viable therapeutic pipeline opportunities in diseases such as MASH, Alzheimer's disease, severe hyperdislipidemia, and several other therapy areas.

Venture capital activity will continue to pick up. Private investments in public equities were up, with 48 privately funded deals of publicly traded companies totaling $4.4 billion in the first half of the year. This was the highest activity seen in one quarter since 2021.[41]

[41] "Trends and Tips for Navigating Life Sciences M&A in 2024," morganlewis.com, May 2, 2024

How KPMG can help

KPMG Deal Advisory & Strategy has a long history of enabling our pharmaceutical clients across the entire transaction cycle:

Where is the growth opportunity and whom to target?

KPMG has a dedicated life sciences team for assessing the landscape of emerging technologies and companies in order to prioritize a short list of company and/or asset targets for business development.

What is the investment thesis and target valuation?

KPMG has specialized teams that can build the forecast models, valuations, and the overall strategic point of view to justify future transactions.

How to integrate?

KPMG has specialized teams dedicated to help pharmaceutical companies develop their integration strategies and then operationalize their integration across all back-office and front-office functions.

To what degree are the financial, commercial, and operational assumptions supporting the investment rationale supported factually?

KPMG life sciences specialists are highly experienced in providing the full range of due diligence services: financial and accounting due diligence, commercial due diligence, operational due diligence, tax due diligence, and human resources due diligence.

How to account and report?

KPMG subject matter specialists are proficient in complex technical accounting and reporting matters, dedicated to helping biopharma companies simplify complex accounting and reporting challenges to help minimize unnecessary risks in financial reporting. We provide practical insights and recommendations on the deal structure and terms, and provide postclose implementation support to assist companies in realizing an accounting and reporting treatment in line with their objectives.

How to divest?

KPMG has experienced strategists to help clients run sophisticated analyses to identify the optimal capital creation options that ensure the financial and strategic goals of the core portfolio are set for growth and sustainability.

Once divestment options are identified, KPMG has experienced teams to support operational separation of the entities across all major functions.

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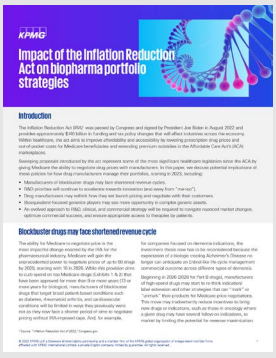

Inflation Reduction Act impact on biopharma portfolio strategies

A new era of precision medicine

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