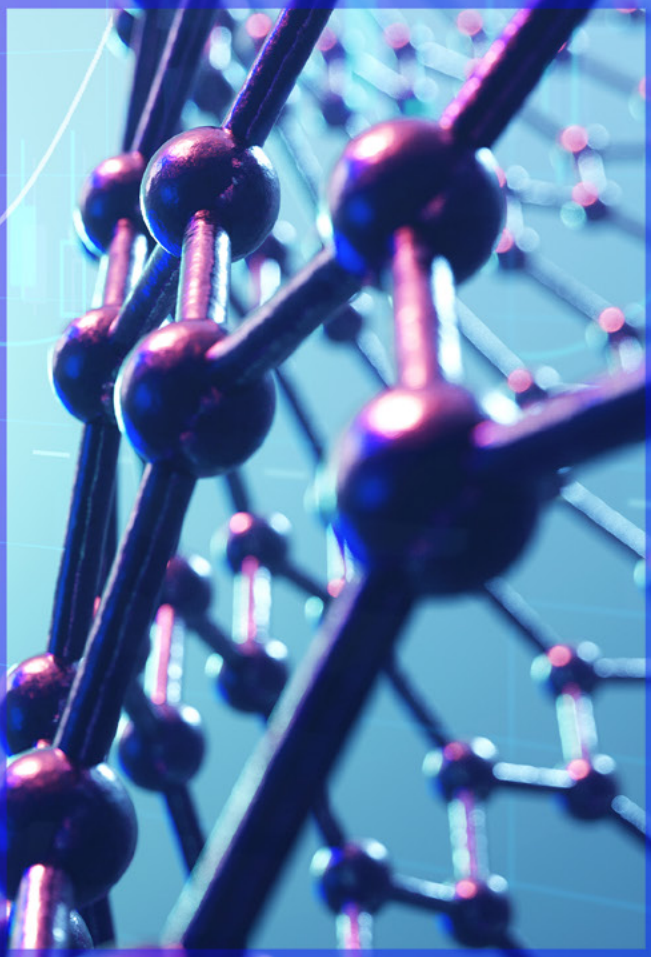
KPMG

Biopharma deal trends outlook for 2023

Near-term headwinds, with possible run on small biotechs on the horizon



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KPMG predictions for the remainder of 2023

Mega-mergers will remain out of favor. While the deal value of the Pfizer-Seagen acquisition makes it one of the larger in the history of the pharmaceutical industry, it fundamentally is more of a platform strategy play versus a true mega-merger (like AbbVie-Allergan) with the potential for significant synergies. We do not anticipate similar size deals in FY23 as the headwinds are increasingly significant, particularly for high-profile deals.

The volume of small to mid-size full-company acquisitions will likely continue to outpace prior years, and we predict that this will be driven by a run on small biotechs in late 2023 and early 2024. We believe the pressure from challenging capital markets will remain unfavorable forcing many of these companies to reconsider their valuation demands.

We believe 2023 will also see the rise of more divestitures and out-licensing deals from large biopharmaceutical companies. After 3 years of very active deal-making, several large biopharmaceutical companies now have very significant early-stage pipelines and are struggling to find the R&D capacity and capital to move those programs forward.

More assertive FTC policies and actions in the merger and acquisition space will continue to affect the industry; however, the FTC's loss in the Meta-Within lawsuit may have positive implications for the biopharmaceutical industry. The next major lawsuits that could have implications for the biopharmaceutical industry are the Amgen-Horizon, Illumina–Grail, and Pfizer–Seagen deals. How the FTC views these three deals and the win or loss of these lawsuits and appeals will shape the deal market for years to come.

Lastly, we believe the implications of the Inflation Reduction Act (IRA) will lead to reduced valuations for certain small-molecule-focused biotech companies because of the 9-year negotiation criteria for high-spend therapies in Medicare Part D and B.

Uncertainties drive slowdown, with notable areas of improvement

The overall biopharmaceutical deal market began to see a significant slowdown in the fourth quarter of 2022 (Exhibit 1), and from a deal volume standpoint this has carried through into the first quarter of 2023 (Exhibit 2). The main driver of reduced deal activity lies in fewer licensing deals and strategic R&D collaborations. There are a multitude of factors likely attributable to this. These include tightening capital and credit markets, and the anticipation that valuations for small to midsize biotechs could fall, particularly as they face funding pressures of economic uncertainty and the shutdown of key mid-market banks that historically have been a source of funding.

Exhibit 1: YoY biopharma deal volume by deal strategy (2017–2022)

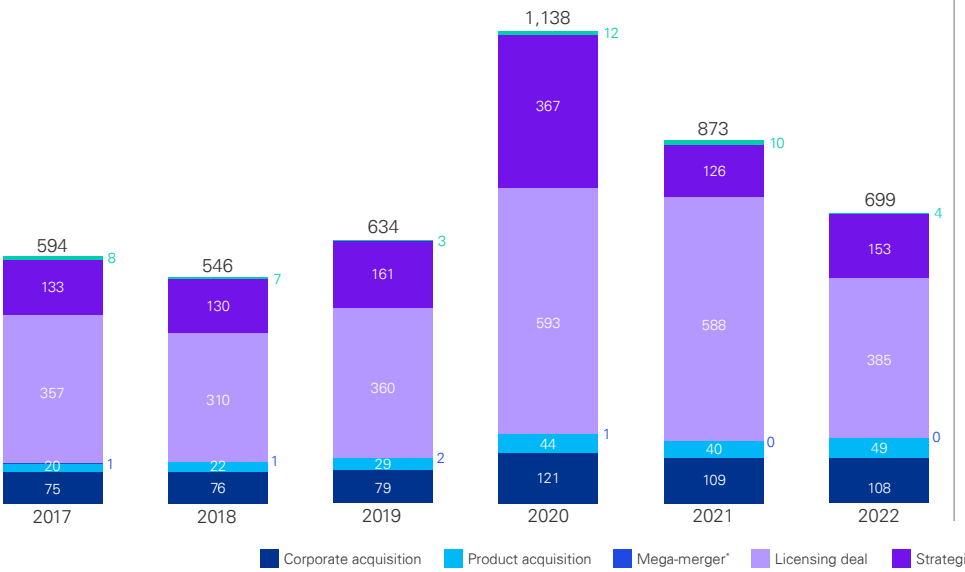
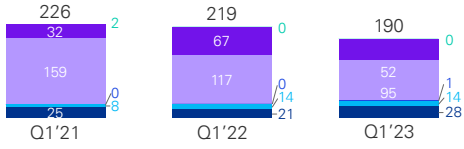


Exhibit 2: Comparison of first quarter deal volume performance (2021–2023)



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 >$30B

Source(s): KPMG analysis; Informa

Despite the overall deal volume being down, there are some notable areas of improvement. Specifically, company acquisitions are on the rise in the first quarter of 2023 compared to the first quarters of the last 2 years, while the total capital deployed for these deals basically remained flat compared to last year's first quarter. This suggests the average price for these acquisitions (excluding Pfizer-Seagen) has been smaller in the first quarter of 2023 than in the first quarter of 2022 (Exhibit 3 and Exhibit 4). We believe this trend is consistent with prior years where the industry has been focused on smaller, more strategic, innovative deals that build pipeline strength.

Exhibit 3: Acquisition volume vs. total deal value of corporate acquisitions (2017-2022)

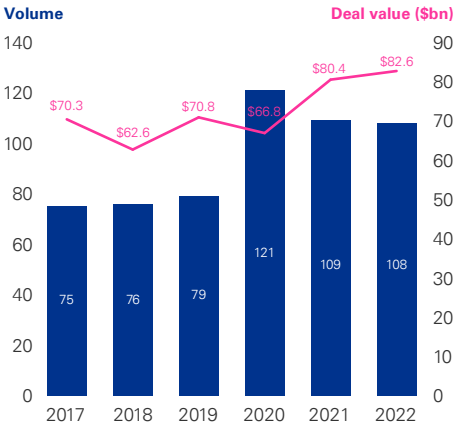
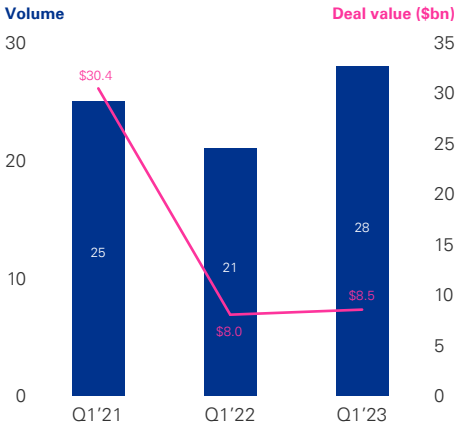


Exhibit 4: Acquisition volume vs. total deal value of corporate acquisitions (Q1 2021-2023)

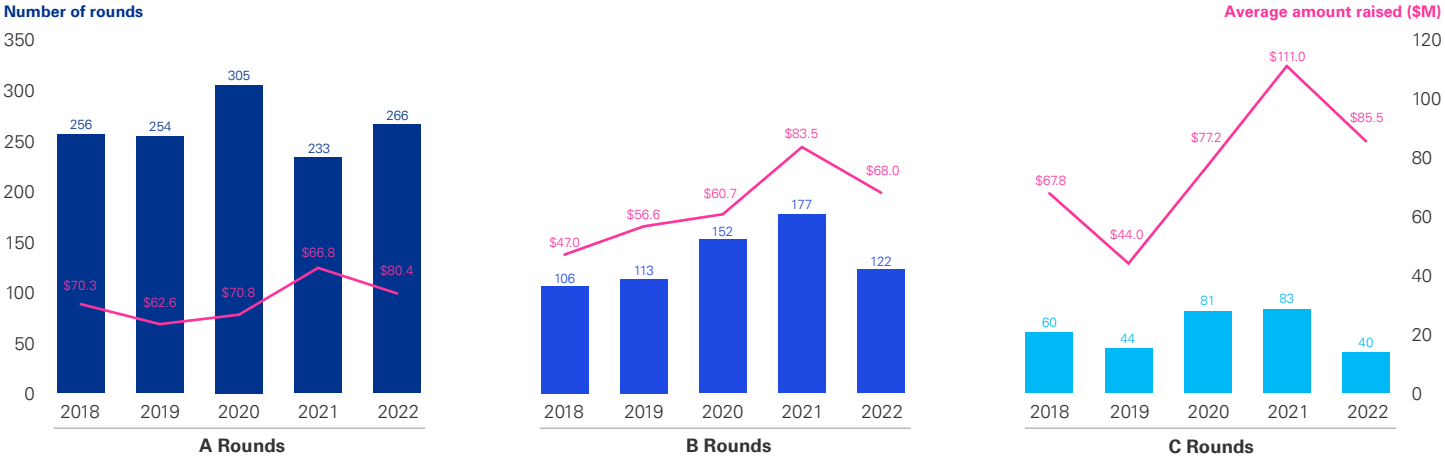


Charts: Mega-mergers (i.e., >$30B) were excluded due to their outlier effect on year to year deal value
Source(s): KPMG analysis; Informa

Given the intense competition for quality assets, it will be interesting to see if this acquisition activity continues through the rest of 2023, particularly as the FTC continues to be active in this space. Several large biopharmaceutical companies face an interesting dilemma: on the one hand, many companies have publicly stated ambitions to increase growth while also improving near- and long-term competitive position across specific therapeutic categories in their pipeline, while other biopharmaceutical companies are facing significant patent cliffs in 2025-2027.[1] The need to build pipelines inorganically is changing for this industry.

We think 2023 will likely continue to be plagued by several headwinds that will slow overall deal activity through the second quarter of 2023 but may lead to a late run on smaller companies' deals in late 2023 and 2024. The headwinds facing the pharmaceutical deal market are multiple, including the passing of the IRA, an increasingly tight capital and private financing market (Exhibit 5), higher interest rates, and an increasingly active FTC attempting to enforce new priorities on M&A. These uncertainties have made it more difficult to execute acquisitions.

Exhibit 5: Private funding trends, rounds A, B, and C (2018-2022)



Source: Precision financing (nature.com)

[1] "Patent cliffs face BMS, Merck, Pfizer but all can pull off M&A," fiercepharma.com, June 21, 2022

Headwind: IRA implications will challenge valuations for certain assets

The IRA has caused pharmaceutical companies to re-examine the assumptions they use to develop forecasts and valuations across a wide range of M&A targets they are considering. Specifically, pipeline assets that are likely to have a significant Medicare Part D and Medicare Part B involvement may be impacted. While these concerns have not halted deal making, for targets without a strong strategic rationale and investment case, the implications of the IRA have made it more difficult to justify certain types of deals until there is more clarity on the range of pricing discounts that will be negotiated under the IRA.

KPMG LLP (KPMG) has discussed the implications of the IRA at length in prior thought leadership papers. One key issue is the policy for small molecule therapies that qualify for Medicare Part D and/or B. Companies that commercialize these types of assets and achieve commercial success with a significant portion of the population having coverage by Medicare will eventually have to negotiate price after nine years. The implications of the new legislation will negatively impact the forecasts for small molecule assets and will directly impact how these types of assets are valued across many important innovative areas of the pharmaceutical industry. Strategically, companies are going to prefer biologic assets that offer 13 years of freedom from price negotiations; however, the need for innovation most likely will not stop interest in acquiring small molecule assets, but it will likely demand that they are acquired at a lower price than they would have been prior to the IRA.

We expect the deal market will likely go through a period where the large pharmaceutical companies that are interested in small biotech companies focused on innovative small molecule technologies, such as mRNA or next generation JAK or SYK inhibitors, will offer lower valuations, while the small biotech companies try to maintain their pre-IRA valuations. It will be interesting to see if this leads to fewer acquisitions of small molecule assets and companies focused on that space, and if we see a shift toward more creative partnerships with milestone options that offer upside if certain commercial goals are met.

Headwind becoming a tailwind?: Private funding market

Access to financial institution capital has become more difficult, and it will continue to shape the deal landscape in 2023. Highly leveraged deals or large deals requiring financing will become much more difficult to execute. Additionally, small to mid-sized biotech companies that need capital to progress key pipeline assets in development will likely find it harder to find funding throughout the rest of this year.

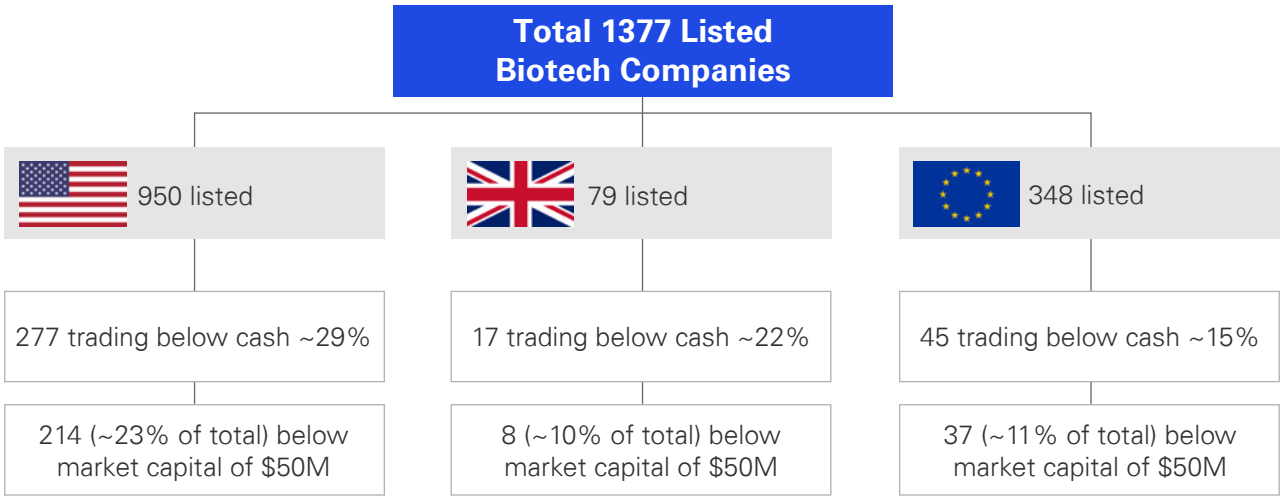
In 2023 and likely into 2024, large biopharmaceutical companies that are well positioned with cash and equity will have a greater advantage competing for targets and will have greater negotiating power particularly in non-competitive deal scenarios. Small biotechs will likely not find as many alternative funding sources.

In 2023, it is unlikely that we will see a return of the highly active private funding markets we saw in 2019-2021. The implications of a more challenging private funding market could end up being a positive in terms of deal activity later in 2023 and early 2024 as biotech companies with attractive clinical stage assets face funding issues. Many of these companies will become hungry for funding, which may finally drive historically high valuations down. This could lead to an active market for large biopharmaceutical companies to either acquire or have more appealing partnership terms later in 2023. This year has already seen some notable trends of public biotech companies now trading below cash value and facing various funding challenges (Exhibit 6). If the financing markets remain tight, by mid to late 2023, biotech companies with higher quality pipelines are likely going to start becoming much more attractive as their valuation demands will be challenged by the need to keep operations sustained.

There is good evidence that first signs of sustainability are hitting the biotech market hard: It has been reported that there has been an 83 percent increase in biotech lay-offs in first quarter of 2023 compared to 2022.[2] Should the funding drought continue to extend through the rest of 2023 (and all signs are that it will), the landscape of biotech companies looking to deal at a discount will grow significantly.

[2] "Layoff Tracker: Layoffs strike 119 companies in 2022," fiercebiotech.com, January 3, 2023

Exhibit 6: Analysis of publicly listed biotech companies trading below cash value (1Q 2023)



Source: KPMG research and analysis; data sourced from Refinitiv

Headwind: Increasingly assertive FTC

KPMG has been anticipating increased FTC activity for the past 2 years. During that time, the FTC has been inching forward in the life science sectors, and by the end of 2022 and into 2023 we are witnessing an uptick in competition scrutiny across the M&A landscape. Several deals have received significant scrutiny, such as Illumina-Grail. Interestingly, Pfizer has engaged in several deals in 2021 and 2022 and appears to have received little scrutiny from the FTC. Pfizer-Seagen is the largest and one of the highest-profile acquisitions the industry has seen since BMS-Celgene and AbbVie-Allergan in 2019. How the FTC reviews the Pfizer-Seagen acquisition will be of major interest across the industry.

There has been speculation that the deal will not be deemed anti-competitive or require any special divestitures.[3] However, recently the FTC sought to block the Amgen-Horizon deal.[4] The FTC's reported concerns include a curious argument that the deal would allow Amgen to "entrench the monopoly positions" of two of Horizon's largest revenue generating medications: the thyroid eye disease treatment Tepezza, and gout medicine Krystexxa. Given that Amgen, prior to the Horizon deal, did not have any commercial or pipeline assets in these specific indications, it will be interesting to see how the FTC intends to defend this position. Amgen does have several products that treat various thyroid-related diseases, so perhaps the FTC is speculating this is where a monopoly could occur. Given the commercial call points for these drugs are often with different physician specialists, it will be interesting to see how the argument unfolds. The Amgen-Horizon deal suit is just the latest for an increasingly active FTC over the last 2 years. The FTC has been very public about its concerns around how M&A in pharma is impacting competition and drug pricing.[5] Is Pfizer-Seagen next?

[3] "Pfizer/Seagen Merger Seems Set To Clear As US FTC Sticks To Traditional Review," Pink Sheet (informa.com), April 29, 2023

[4] "FTC sues to block Amgen acquisition of Horizon Therapeutics," CNBC.com, May 16, 2023

[5] "FTC chair Lina Khan to Senate: Big Pharma M&A is still a priority target," Endpoints News, September 21, 2022

Deep Dive: The implications of FTC policy, and key lawsuits and appeals

Since 2020, the FTC under Lina Khan's leadership has increasingly taken on a more proactive and restrictive approach to how it reviews the anti-competitive implications of various acquisitions. As KPMG has discussed in previous papers with input from Goodwin Procter LLP,[6,7] the FTC is taking more time to review most acquisitions. The agency is also pursuing new policy and litigation approaches that, if successful, could lead to a major slowing of M&A activity and could change how the pharmaceutical industry builds portfolios and unlocks early-stage innovation. In this context, two non-pharmaceutical industry anti-trust suits in 2023 are worth monitoring closely.

First, it looks like there is a growing alignment between the FTC and the UK's Competition and Market Authority (CMA). Of note, there was a highly publicized meeting between Lina Khan and the head of the UK's CMA. One week after that meeting, the CMA revised its decision on the Microsoft-Activision acquisition and blocked it. While FTC and CMA have denied discussing this deal during their meeting, the decision by CMA surprised many because initially the CMA's commentary that the competition concerns had been addressed[8] signaled the CMA was likely to approve the deal. Additionally, the CMA compared to the FTC has historically been less restrictive and active on managing M&A.[9] While this decision is not final (Microsoft recently won its EU appeal[10]), the deal represents a notable instance of when the FTC (which brought a lawsuit against Microsoft on this deal in December 2022) and the CMA, at least in appearance, aligned on trying to prevent an acquisition. If the FTC's decision is upheld, it could create a precedent for which types of acquisitions are considered anti-competitive, changing the bar for what types of deals are considered pro- versus anti-competitive.

The second FTC case that could have significant implications for the pharmaceutical industry is Illumina-Grail.[11] As background, Grail was founded in 2015 by Illumina and was initially wholly owned by Illumina. In 2016, Grail was spun out of Illumina (maintaining 12 percent ownership)[12] to enable Grail to become more entrepreneurial and access alternative sources of funding necessary for it to develop and commercialize its novel, early detection, liquid biopsy platform. Fast forward to 2021, when Illumina re-acquired Grail and highlighted that its larger commercial scale would enable more patients globally to access this important technology. However, the FTC sued Illumina claiming the acquisition would "diminish innovation in the U.S. market for M.C.E.D. tests," multi-cancer early-detection tests, while "increasing prices and decreasing choice and quality of tests."[13] At present, the FTC is requiring Illumina to divest Grail. The final appeals decision is expected later in 2023, and should Illumina lose its final appeal, the implications for big pharmaceutical companies are multiple.

First, this could greatly impact various types of divestiture activity in the future. Specifically, one tried-and-true strategy large pharmaceutical companies have deployed to unlock the value of early-stage assets they have either developed themselves or amassed through acquisitions is through structured divestitures. The divestiture structures often have explicit or unwritten intents to have the option of bringing those assets back into their portfolios at a later date should the asset achieve certain development milestones.

[6] "Biopharmaceuticals deal trends: What to expect in 2021," KPMG LLP, 2021

[7] KPMG 2022 HCLS Investment Outlook

[8] "UK blocking of Microsoft-Activision deal surprises Wall Street analysts," Seeking Alpha, April 26, 2023

[9] "Microsoft's bid to buy Activision Blizzard clears a key hurdle. But the $69B deal is still at risk," ABC News, May 15, 2023

[10] Ibid.

[11] "F.T.C. Orders Gene-Sequencing Company Illumina to Divest Acquisition," The New York Times, April 23, 2023

[12] "Illumina Acquires GRAIL to Accelerate Patient Access to Life Saving Multi-Cancer Early Detection Test," Illumina.com, August 18, 2021

[13] "F.T.C. Orders Gene-Sequencing Company Illumina to Divest Acquisition," The New York Times, April 3, 2023

Deep Dive: continued

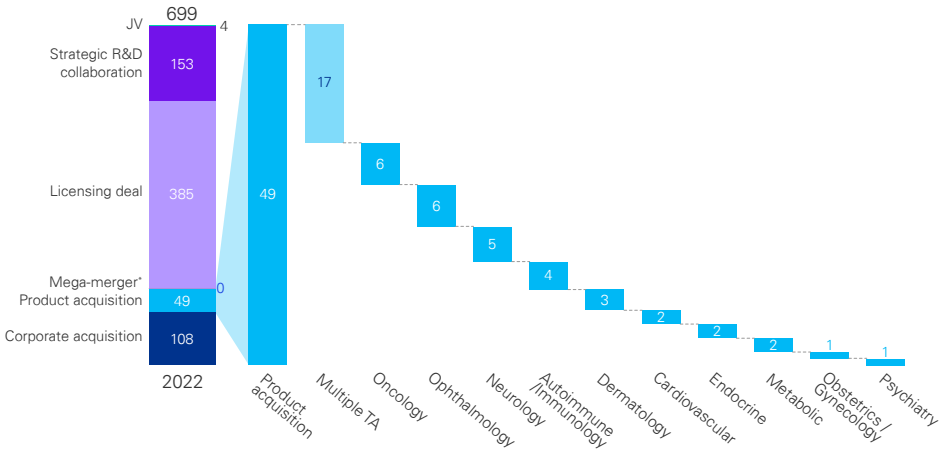
These divestiture strategies are immensely important to the innovation ecosystem of the pharmaceutical industry. Every year, large pharmaceutical companies engage in a pipeline review and determine which assets to prioritize for internal funding, which assets to pause, and which assets to either divest or terminate. Often, the decision to divest does not mean the company is no longer interested in the asset. Rather, it is a recognition that every company has a limited amount of financial and human capital it can deploy toward its pipeline assets. Early-stage assets, which inherently are higher risk and have longer development timelines, are frequently deprioritized for mid- to late-stage assets. As such, this mechanism of divesting early-stage assets is essential for these entities to find external funding and scientific resources so they can progress to later stages. It appears that if the FTC ultimately wins the Illumina-Grail case, that could lead to a chilling effect on these types of divestitures, ultimately leading to fewer innovative assets progressing to commercial stage. If this occurs, it could both hurt future revenues of large pharmaceutical companies and may also prevent a portion of early-stage drugs from reaching patients.

The second potential impact on the pharmaceutical industry if Illumina loses its appeal is specific to the pace of global adoption of early-detection liquid biopsy technology. Illumina is one of the few companies with the global infrastructure, reach, and know how to globally commercialize these types of new technologies. In parallel, the pharmaceutical industry has invested in numerous new cancer therapies pursuing indications associated with early detection via liquid biopsy. One possible outcome should the FTC succeed in blocking the Illumina deal is that the pace of global access to these early detection tests will be slowed, negatively impacting both future revenue for the drugs linked to this technology, and impacting the ability of new, life-saving drugs reaching patients.

Where have biopharmaceutical companies been hunting?

In recent years, oncology has largely been the most therapeutic area for deal activity; however, in 2022 from a product acquisition standpoint (Exhibit 7), we saw assets with the potential of multiple indications (non-oncology) outperform oncology deals. Qualitatively, this trend aligns with what KPMG has seen in the deal landscape. While the demand for adding new oncology assets to pipeline portfolios remains a top priority for many large to mid-sized pharmaceutical companies, the availability of quality assets has become increasingly scarce because the competition for these assets has largely consumed all the quality mid- to late-stage oncology assets from the global pipeline.

Exhibit 7: Volume of product acquisition deals, by therapeutic area



Source(s): KPMG analysis; Informa

The only way to truly access high-quality, mid- to late-stage oncology assets is through co-promotions or a very large acquisition like Pfizer-Seagen or BMS-Celgene. And as we have seen over the last 3 years, the appetite across the industry for deals north of $30 billion has been marginal. The majority of asset deals have occurred in early stages of development. Currently, there is a dearth of available quality mid- and late-stage assets in oncology, which has led to other therapeutic areas attracting a lot more attention. The data for 2022 demonstrates this trend with deals focused on therapeutic areas such as ophthalmology, neurology, and immunology.

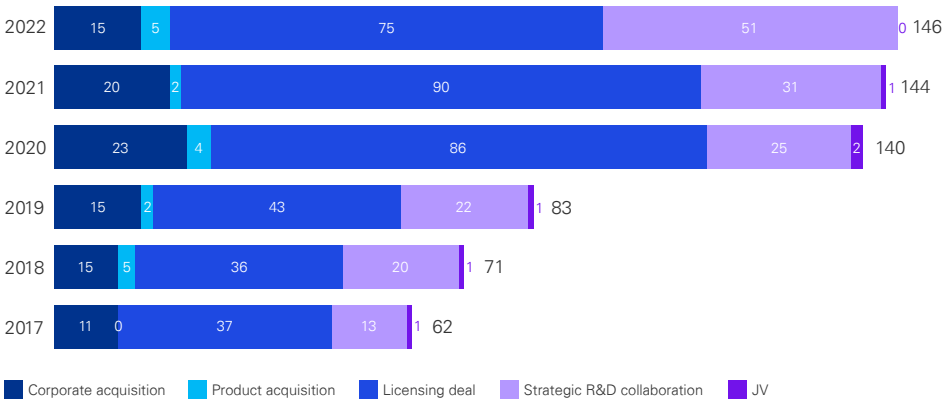
The other area we have seen significant deal focus by the industry has been in cell and gene therapy (Exhibit 8), which is almost entirely focused on rare diseases. Last year saw continued growth in terms of the number of deals focused in cell and gene therapy, and proportionally cell and gene deals made up a greater number of the total deals executed than in any prior year. In our 2022 biopharma deal trends report[14] we anticipated that the industry could pull back in terms of the number of full company acquisitions in 2022, which we eventually saw this in the data. Our rationale for anticipating this pull back was that in recent years large pharmaceutical companies have struggled to see the return on investment from gene therapy companies they have acquired. The failure of some high-profile acquisitions has ranged from extremely poor integration

[14] "Biopharma deal trends outlook for 2022," KPMG LLP, 2022

implementation to late-stage asset failures (see Astellas-Audentes).[15] The culmination of these issues has led to an industry-wide reconsideration of how to optimally engage with these next-generation opportunities and how to de-risk the investments they make. The potential of cell and gene therapies remains immense, but solving the talent and execution issues related to manufacturing, supply chain, and R&D remain significant obstacles for the industry to solve.

The data in 2022 documents this trend of reconsidering strategies for deals that allow for greater risk sharing (Exhibit 8), and in the first quarter of 2023 (Exhibit 9) a similar trend is reflected. Specifically, the data shows fewer full company acquisitions, and an increase in the number of strategic R&D deals. These R&D collaborations have typically focused on creating longer-term milestones for the cell and gene therapy biotechs to achieve before the larger pharmaceutical companies trigger the option to increase investment, own, or partner commercially. This trend toward deal strategies that look to mitigate the risk of cell and gene investments has continued in 2023. This is an interesting contrast to the broader deal market of the first quarter of 2023, which has actually seen an increase in company acquisitions compared to prior years (Exhibit 2).

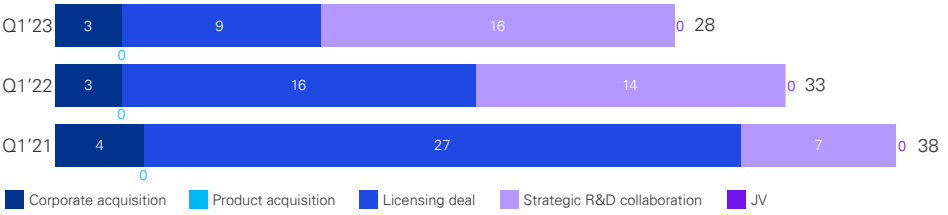
Exhibit 8: YoY cell and gene therapy (CGT) deals (2017-2022)



Year	*2022*	*2021*	*2020*	*2019*	*2018*	*2017*
Total Deals	699	873	1,138	634	546	594
% CGT	21%	16%	12%	13%	13%	10%

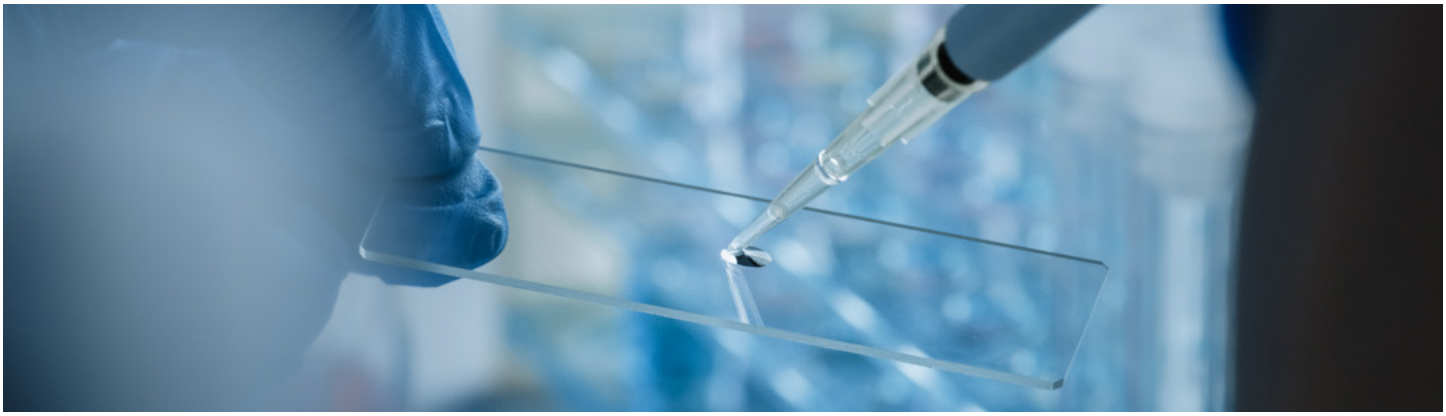
Source(s): KPMG analysis; Informa

Exhibit 9: First quarter deal volume comparison (2021-2023)



Quarter year	*Q1'23*	*Q1'22*	*Q1'21*
Total Deals	190	219	226
% CGT	15%	15%	17%

Source(s): KPMG analysis; Informa



[15] "Another death blights Astellas' $3B Audentes buy as FDA slaps clinical hold on the test," Fierce Biotech, September 14, 2021

Final thoughts

01

The 2023 deal market started off looking considerably different than any prior year in recent memory. While some trends remain similar, such as lack of appetite for mega-mergers, overall deal volume appears to have slowed.

02

The need to continue to build pipelines inorganically remains an existential need for most of the large to mid-sized players across the pharmaceutical industry, and this should maintain some degree of deal flow despite the current unfavorable financial markets.

03

We are seeing several signals that suggest small biotech companies will likely face significant issues with financing in 2023 and 2024, and this may mean valuations for a portion of biotech companies will see a decline as the second half of the year unfolds. In the segment of biotechs with the highest-quality assets, however, we expect deal competition to sustain higher valuations.

04

We believe the pharmaceutical industry will reduce its interest in certain types of targets. For example, the industry's appetite for autologous cell therapy platforms has been diminished as the competitors in this space have struggled with operations and profitability of these drugs. However, interest in other innovative areas where manufacturing and supply chain complexity is less cumbersome should see growing competition.

05

Perhaps the most important issue that will shape 2023 and beyond is found within the Inflation Reduction Act (IRA). Prior to the IRA, the competition for therapies like RNA-based pipeline drugs was likely going to intensify; however, given many of these drugs are considered small molecule therapies (and can be impacted by price negotiation), there may be a temporary slowdown as buyers and targets battle over valuations.

06

Oncology will continue to be a therapeutic area of high interest for the pharmaceutical industry. However, finding quality assets in oncology will remain challenging unless there is a willingness to consider pre-clinical platforms and Phase I opportunities.

07

Companies will continue to broaden their deal focus to a wider array of therapeutic areas because the need to fill pipeline gaps and have options for future revenue growth will necessitate a broader focus.

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 who to target?

KPMG has a dedicated life science 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's 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.

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

How to integrate?

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

How to divest?

- KPMG has expert strategists to help clients run sophisticated analyses to identify the optimal capital creation options that help entities set up their financial and strategic goals of their core portfolios for growth and sustainability.
- Once the divestment options are identified, KPMG has specialized teams to support the operational separation of the entities across all major functions.

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