

How life sciences companies can secure value through better dealmaking

2023 EY M&A Firepower report



Building a better
working world

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Welcome

As we enter 2023, we believe that we are entering a new phase of large-scale dealmaking in the life sciences industry. This 2023 edition of the *EY M&A Firepower report* sets out the rationale to expect increased mergers and acquisitions (M&A) activity; with the report going to press in mid-December, we saw what may be the first sign of the industry accelerating on that trajectory, with Amgen's acquisition of Horizon Therapeutics for US\$28.5 billion. This was comfortably the biggest biopharma deal of 2022, and followed the year's biggest MedTech deal, Johnson & Johnson's US\$16.6 billion buyout of Abiomed.

What will drive dealmaking in the year ahead is the quality of the assets available. There remains a significant number of high-quality targets in the market: companies developing new pharmaceutical modalities such as cell and gene therapy and mRNA-based therapeutics, companies breaking new ground with digital technologies and data that have the potential to transform how we deliver personalized care in the home and other non-traditional settings.

Companies offering these kinds of high-potential innovations will create the most value for the long term, and as a "buyer's market" takes shape, these companies will need to be able to communicate their story and demonstrate that they are ready for the next step in the journey. As the industry's leaders look to secure growth in a volatile macroeconomic and geopolitical landscape, with loss of exclusivity for key products looming, M&A will be as vital as ever for securing innovation.

To secure value in the future, the industry's focus on innovation will need to extend beyond drugs and devices to embrace wider transformation of business models. Ultimately, life sciences companies that succeed will be those that adapt to meet patient demand for a more personalized health experience and outcomes, as a more connected "Intelligent Health Ecosystem" evolves. As we look ahead, we can state confidently that the fundamentals of the industry remain strong - and the right strategic deals will continue to get done into 2023 and beyond.



A handwritten signature in black ink that reads "Subin Baral".

Subin Baral
EY Global Deals Leader, Life Sciences

“

The right deals are getting done
irrespective of valuation.



EXECUTIVE SUMMARY

Innovation remains at the heart of the life sciences industry, and we are currently living through a resurgence in new research breakthroughs across the sector. From new modalities in biopharma (from cell and gene therapy to mRNA platforms and beyond) to the increasing adoption of digital technologies and data science, innovation is transforming the sector. Among life sciences companies, the leaders will be those that set the pace of change.

Dealmaking will be an increasingly major strategic consideration for life sciences players. This does not necessarily mean acquisition moves to take outright ownership of new technologies. The critical imperative is access to innovation, and companies will need to form or expand alliances and partnerships to achieve forward progress. And with timing always a critical component, in some cases embracing collaboration rather than control could be the template for progress.

In the past year, we have seen a downturn in dealmaking, with companies holding deep reserves of Firepower (which EY teams define as a company's capacity to do M&A based on the strength of its balance sheet) yet choosing not to deploy it. But as companies seek to secure growth and future-proof their business models amid a rising tide of innovation, M&A will need to take a central strategic role.

We see three major themes that will shape how the life sciences industry uses its Firepower in 2023 and beyond:

1. The industry's leading players face significant upcoming growth gaps, particularly because of patent expiries looming in the biopharma sector, but have the Firepower to close these gaps through dealmaking.
2. Political, economic and regulatory uncertainties are affecting the industry's deal appetite, but corrections in valuations and declining initial public offering (IPO) and special-purpose acquisition company (SPAC) opportunities are creating a "buyer's market," which will prompt the big players to invest in deals.
3. The most important targets are not only the novel drugs and devices that offer immediate value, but also the innovative technologies emerging outside the sector, including breakthroughs in artificial intelligence (AI), big data, robotics and others.

The life sciences industry must continue to realize value from innovation, but in the longer term we can expect the nature of this innovation to shift as data and digital tools are increasingly integrated into care provision.

As these changes accelerate, life sciences companies will need to rethink their business models to adapt to the emergence of an intelligent health ecosystem that can deliver more efficacious, cost-effective, personalized care to patients. Dealmaking - M&A and agile collaborations to

access innovation both within and beyond the life sciences sector - will play a critical role in how companies evolve and thrive within this new and evolving ecosystem. In a longer perspective, 2022 may come to be recognized as the calm before the storm; the dealmaking dip has the potential to become a dealmaking deluge in 2023, as companies seek innovation not just in their portfolios but across their entire operating models.

Key definitions

Term	Definition
Firepower	A company's capacity to fund strategic initiatives, including transactions based on the strength of its balance sheet. It has multiple inputs: cash and equivalents, existing debt and market capitalization.
Deployed Firepower	The ratio of capital spent on M&A and/or alliances relative to available Firepower.
Growth gap	The difference in US dollars of a biopharma's sales growth relative to overall drug market sales.
Megadeals	Acquisitions with valuations of roughly US\$40 billion (biopharma) and US\$10 billion (MedTech).
Bolt-on	Small-to medium-sized acquisitions that account for less than 25% of the buyer's market capitalization.
Financial deal	Transactions involving a financial buyer such as private equity.
Transformative deal	Transaction in which the deal value is greater than 50% of the acquirer's market capitalization at the time of purchase.

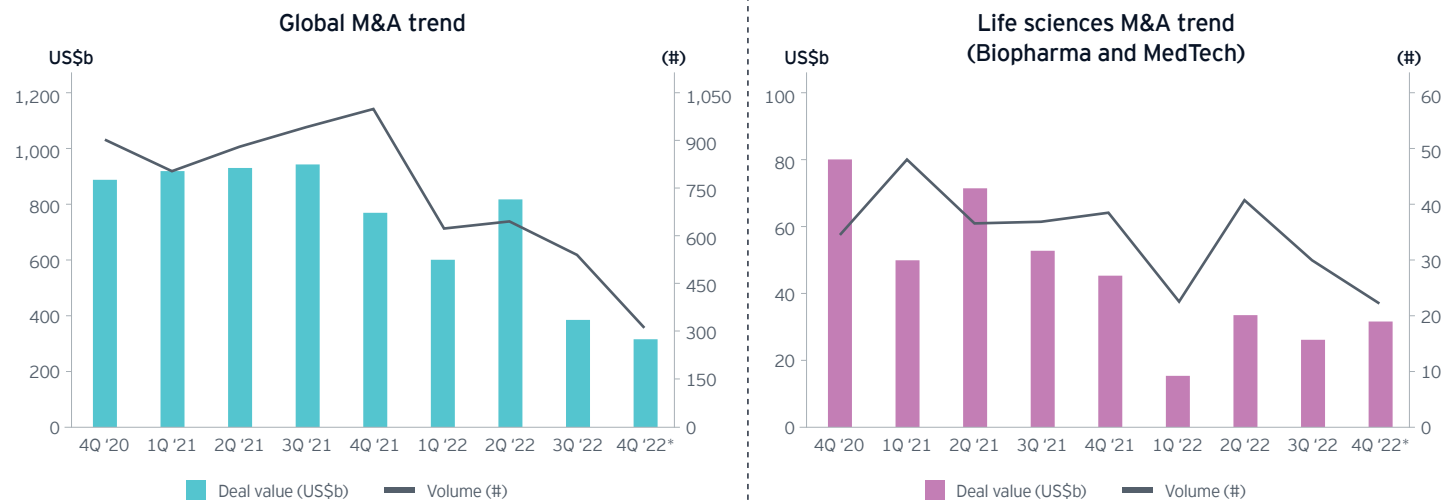




**IN THE
SHALLOWS:
2022 IN REVIEW**

With only US\$105 billion in M&A deals completed up to the end of November 2022, the life sciences sector is on pace to recorded its lowest dealmaking year by value since 2017. Overall, M&A investment for 2022 YTD has fallen 53% compared to the full year of 2021. In all, 117 deals were signed, a 27% decline compared with 2021. The overwhelming majority of this year's deals have been bolt-on deals of small scale. This aligns with broader global dealmaking trends for all industries, with an overall drop in 2022 M&A investment worldwide (see Figure 1), reflecting the disruptive uncertainties of ongoing geopolitical conflicts and macroeconomic volatility.

Figure 1: Quarterly M&A deal value and volume trends, Q4 2020-Q4 2022 YTD



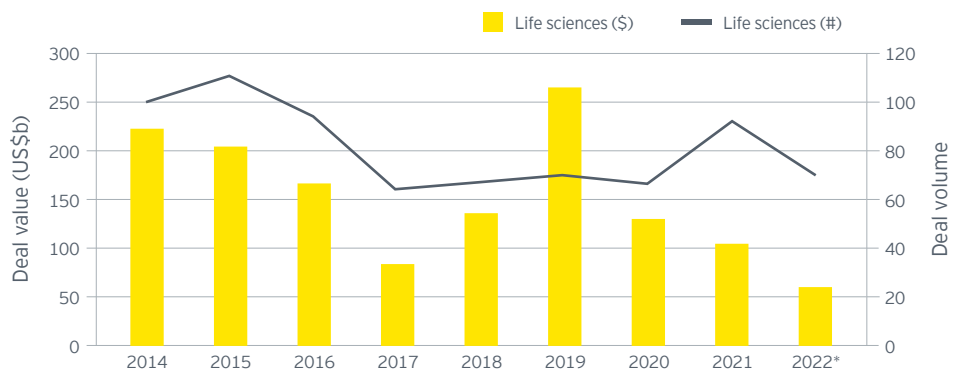
Source: Capital IQ, EY analysis | Note: M&A deals above US\$100mn analyzed and categorized basis on announcement date. | * Includes deals until 30 November 2022.

In the biopharma sector, the lack of dealmaking activity in the first 11 months of 2022 was particularly striking, with M&A spend the lowest since the *EY M&A Firepower report* was first published (see Figure 2).

Despite the global uncertainties, the life sciences industry has strong structural factors favoring M&A. In our previous *EY M&A Firepower report* (January 2022), we cited some of the major factors constraining dealmaking in 2021:

- ▶ Record-level valuations and high premiums for biotech targets as the industry drew considerable investor attention during the early stages of the pandemic.

Figure 2: Total biopharma M&A value and volume, 2014-2022 YTD



Source: Capital IQ, EY analysis. Only deals with publicly disclosed values greater than US\$100 million were considered for this analysis. * Q4 data as of 30 November 2022.

- ▶ High capital liquidity with smaller companies enjoying easier access to public markets via IPOs, SPACs and venture capital (VC) funding.

Six months later, these constraints had largely disappeared. A plunge in biotech valuations saw a corresponding drop in biotech financing, with the record IPO market of 2021 declining alongside the SPAC market. This will complicate the route of small companies to the public markets and should make M&A exits more appealing.

Yet, the shift in financing has not prompted most major life sciences players to return to dealmaking. In the biopharma sector (see Figure 3) deal value fell 42% compared with 2021, with Pfizer's acquisition of Biohaven the single largest deal prior to December 2022.

We also noted last year the continued importance of partnerships and strategic alliances, which have taken an increasingly large share of biopharma capital deployment in recent years. Alliances remain a significant focus for biopharma (see Figure 4), and companies' M&A strategies.

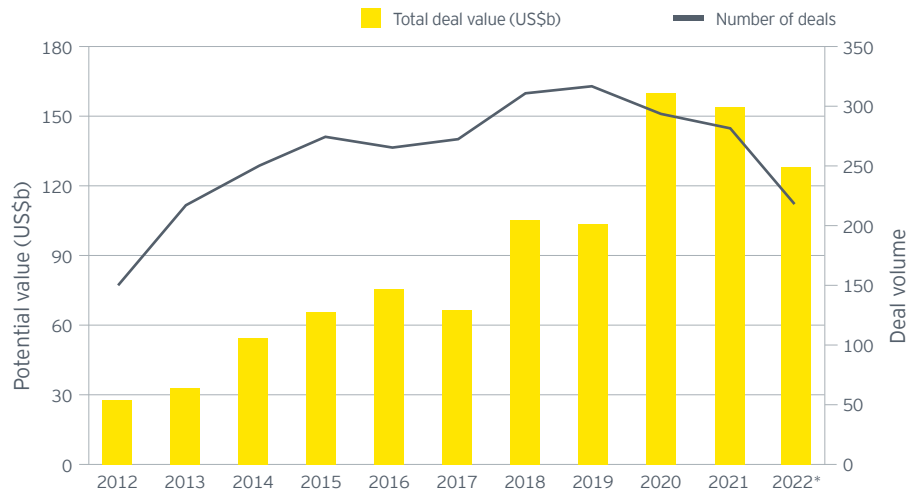
The barriers to large-scale M&A investment largely have fallen, yet the big life sciences players are still holding back, though perhaps not for much longer. On 12 December 2022, Amgen announced it will pay US\$28.5 billion to acquire Horizon Therapeutics, which markets the thyroid ocular disease blockbuster Tepezza (teprotumumab-trbw). The deal falls outside the scope of this report's data and will likely be finalized in the first half of 2023. As we will discuss below, there are strong reasons to suspect Amgen will not be the only big player making a return to the big dealmaking table in 2023.

Figure 3: Biopharma quarterly M&A deal value and volume trends



Source: Capital IQ, EY analysis
 Note: M&A deals above US\$100mn analyzed and categorized basis on announcement date.
 * Includes deals until 30 November 2022.

Figure 4: Biopharma strategic alliance investment, 2014-2022*



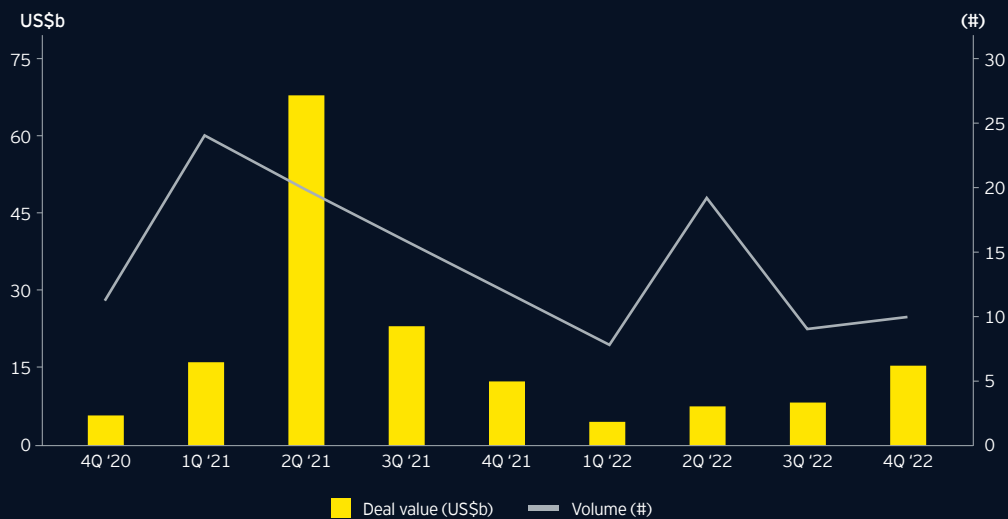
Source: EY analysis, Biomedtracker. Chart shows potential value, including upfront and milestone payments, for alliances where deal terms are publicly disclosed.
 * Includes deals until 30 November 2022.

The MedTech sector experienced a huge M&A surge in 2021, with more than US\$119 billion invested in dealmaking. This influx was an outlier, driven by three major deals that constituted more than 50% of the total value:

- ▶ The US\$34 billion acquisition of a majority share of Medline Industries, by Blackstone, Carlyle and Hellman & Friedman
- ▶ Thermo Fisher Scientific’s US\$16.8 billion acquisition of PPD
- ▶ Baxter’s buyout of connected care specialist Hillrom for US\$10.5 billion

MedTech M&A value fell 62% in 2022 (see Figure 5), while the overall volume of deals fell by 35%. However, the fourth quarter significantly lifted the overall deal value for the sector, with Johnson & Johnson’s US\$16.6 billion acquisition of Abiomed, a heart recovery specialist company, representing about 42% of the total MedTech M&A spend for the year. This deal was also the second largest M&A deal in the life sciences as a whole in 2022.

Figure 5: MedTech M&A trends Q4 2020-Q4 2022* YTD



Source: Capital IQ, EY analysis

Note: M&A deals above US\$100mn analyzed and categorized basis on announcement date. | * Includes deals until 30 November 2022.

MedTech is facing industry-specific headwinds, which may pause companies’ enthusiasm for significant M&A investment. While surgical procedures have resumed in the wake of COVID-19, staffing shortfalls across the health care sector may make it difficult for hospitals to maintain procedure volumes, or drive up hospital payroll costs, leading to potential cutbacks in procurement of medical devices and other capital equipment.

Broader financial trends are also a factor. As John Babitt, EY Americas MedTech Transactions Leader, noted in our 2022 Pulse of the Industry report (which contains more detailed analysis of the MedTech sector and its performance in 2021-22), “Continued uncertainty in the overall financial markets continues to weigh on the M&A appetite; the overall MedTech M&A and innovation ecosystem continues to remain intact, but near-term storm clouds are likely to pause transactions volumes into 2023.”

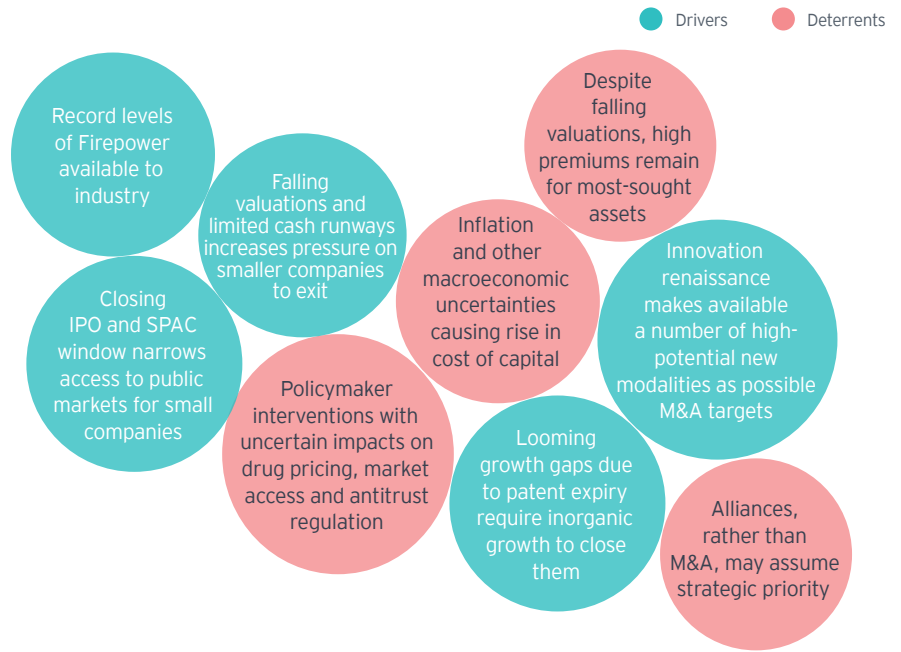
A hand is shown from the bottom, with the index finger pointing upwards. A single water droplet is suspended in mid-air, just above the tip of the finger. The background is a calm lake reflecting the sky and surrounding trees. The sky is a mix of blue and orange, suggesting a sunset or sunrise. The water's surface is slightly rippled, and the reflection of the hand and the droplet is visible in the water below. A yellow rectangular box is superimposed over the upper part of the image, containing the text.

WILL THE TIDE
TURN IN 2023?

In 2023, the life sciences industry is likely to move toward large-scale transformative dealmaking, potentially heralded by Amgen’s multi-billion move for Horizon. The main obstacles to dealmaking are the impact of macroeconomic factors such as rising inflation and currency volatility - M&A financing is more complex against a background of ascending interest rates and inflation - and the impact of legislation in the US (see our guest perspective from Heather Meade, Principal, Washington Council Ernst & Young, on “What life science leaders should watch in a divided Washington”).

Despite these challenges, there are strong underlying reasons for companies to adopt a more aggressive M&A strategy (see Figure 6).

Figure 6: Drivers and deterrents on life sciences dealmaking in 2023

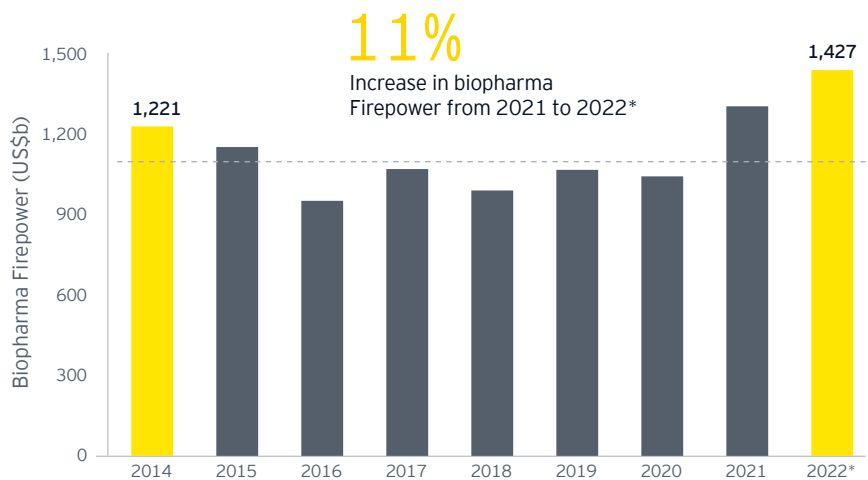


The five factors driving the life sciences industry to use its Firepower

FACTOR ONE: The life sciences industry has deep reserves of Firepower.

At the end of November 2022, the biopharma industry alone held more than US\$1.4 trillion in Firepower: an 11% increase on 2021, and the highest level recorded since the *EY M&A Firepower report* began tracking biopharma’s deployable capital (see Figure 7).

Figure 7: Life sciences Firepower levels, 2014-2022*



Source: Capital IQ, EY analysis. | *Firepower as of 30 November 2022.

FACTOR TWO: The industry faces looming growth gaps, particularly regarding biopharma patent expiries.

Based on current projections, the biopharma industry is set to experience significant revenue erosion over the next decade, as leading products lose patent protection and face competition from lower-priced generic and biosimilar challengers (see Figure 8). In the past two years leading life sciences players have increasingly sought to de-merge business units, spinning out or announcing their intention to spin out generics units (Pfizer and Novartis) and consumer health businesses (GlaxoSmithKline and Johnson & Johnson). Focusing on their core innovative biopharma businesses will mean companies need strong pipelines and a deep therapeutic focus to realize value, which will give them further incentive to seek high-value acquisitions.

FACTOR THREE: There is an ongoing innovation renaissance in the life sciences sector, which offers companies potential access to products that can secure their future growth.

The life sciences sector is expected to undergo a significant surge in innovation, with multiple new therapeutic modalities reaching the market, including cell and gene therapies and the mRNA platform, which enabled the rapid development and modification of COVID-19 vaccines.

Beyond traditional drug and medical device technologies, there are also emerging opportunities to use digital technologies and data analytics in ways that can potentially transform health care. MedTech has already taken steps in this direction (witness Baxter’s 2021 acquisition of Hillrom). The potential of these new approaches to transform care and drive future growth will be

a major imperative as the industry continues to evolve toward an intelligent health ecosystem. Scientific innovation alone, whether in the form of new drugs or devices, is unlikely in the future to be able to achieve the high returns the industry expects. There is a greater need to deliver better and more personalized outcomes and to validate these results. This will involve greater use of companion diagnostics and other digital tools to demonstrate effectiveness. Companies will need to reach beyond their traditional operating models and silos and build new partnerships and alliances to achieve recognition for the value of their innovations and help ensure appropriate reimbursement from payers.

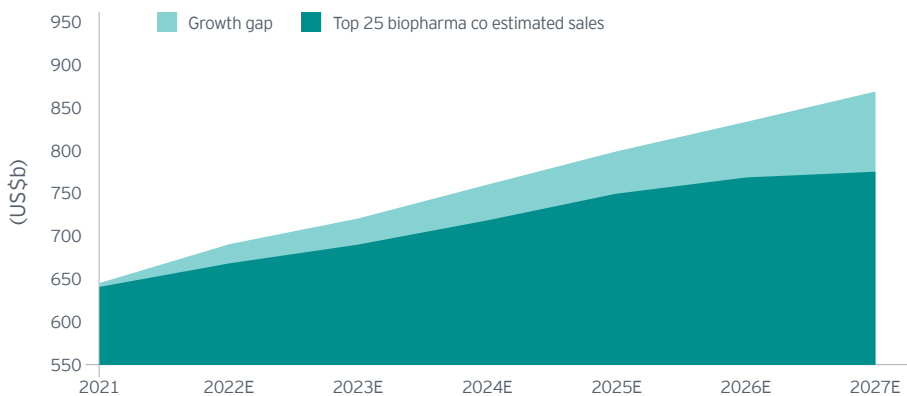
FACTOR FOUR: Following the market corrections of 2021-22, the high valuations of target companies should become less of an obstacle.

The drop in biotech valuations has yet to trigger a surge in dealmaking. However, given the pressures of growth gaps and the potential gains from accessing new modalities and innovations, life sciences companies have urgent motivation to make deals. The valuation drop in the sector will increase the incentives, as a “buyer’s market” takes shape.

FACTOR FIVE: Smaller life sciences companies also have reduced access to public markets as IPO and SPAC funding becomes more challenging, increasing the likelihood of M&A exits.

The rapid decline of the life sciences IPO market narrows the options for smaller companies. The need for financing will drive smaller companies toward M&A.

Figure 8: Growth gap analysis



Source: EY analysis, Evaluate Pharma.
 Note: Growth Gap analysis is based on October 2022 Evaluate Pharma data and excludes the impact of COVID-19 vaccines and therapies, which are forecast to have maximum impact between 2021-23 and moderate impact from 2023-27.



Convergence and competition in life sciences investment

Another dealmaking incentive is that life sciences companies may face competition in the M&A space from acquirers from outside the sector, and risk missing growth opportunities if they fail to make a move.

For example, PE funds have Firepower to deploy and are likely to continue seeking acquisitions in the life sciences sector. Some analysts have suggested that PE may increasingly take over from traditional life sciences companies in funding drug development and other areas of R&D. For more discussion of this subject, see our guest perspective from Lisa Huang, Principle in the Blackstone Life Sciences group.

M&A moves elsewhere in the health sector show providers and tech companies investing in new care models, with deals including:

- ▶ Tech giant Amazon's US\$3.9 billion acquisition of technology-driven primary care provider One Medical in July 2022
- ▶ CVS Health's September 2022 US\$8 billion acquisition of Signify Health to bolster its capabilities in home-based care delivery
- ▶ Walgreens' approximately US\$392 million purchase of CareCentrix, a post-acute and home care leader, in October 2022

M&A deals of these kinds are reshaping the ecosystem within which life sciences companies operate. The convergence of sectors and technologies will increase the pressure on life sciences players to make deals that can secure their future growth as the sector continues to evolve toward the emergence of an intelligent health ecosystem.

HOW CAN LIFE
SCIENCES AND
WELLNESS COMPANIES
DO BETTER DEALS?



Given the strong underlying reasons for life sciences players to seek growth through dealmaking, but also the relatively high level of uncertainty in the operating environment, it is imperative that companies give serious strategic thought to how to identify and execute the most effective M&A moves possible. We see three main areas where companies can seek to gain the maximum value from deals:

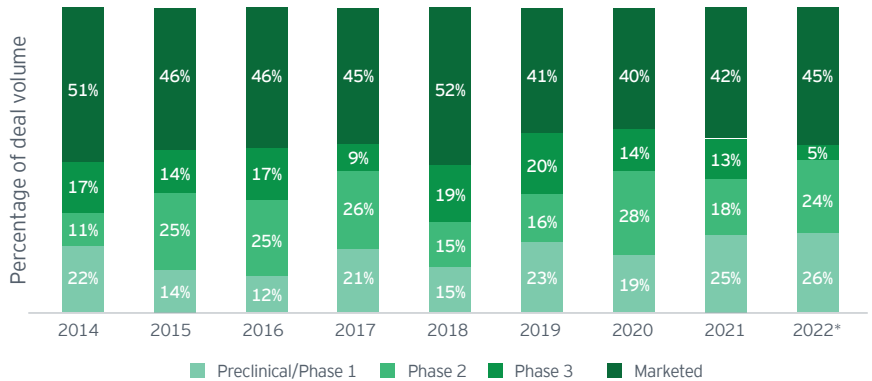
1. Attempt to de-risk deals as far as possible.
2. Analyze what kinds of deals have worked successfully in the past.
3. Have good processes in place to integrate new acquisitions.

De-risk deals or get in early

Biopharma companies have long aimed to remove some of the risk factor from M&A by concentrating their Firepower on late-stage, relatively well-validated clinical assets, and focusing on therapeutic areas with high growth projections (see Figure 10). In terms of choosing targets, data indicates that biopharmas are increasingly moving toward earlier-stage assets: pre-Phase III targets made up 50% of M&A deal volume in 2022, for the first time since *Firepower* began. Biopharmas clearly recognize that they must pay a premium for de-risking acquisitions or move earlier in the R&D cycle to access innovations.

In recent years, the main therapeutic area targets have been in oncology, immunology, central nervous system (CNS) and infectious diseases (see Figure 10).

Figure 9: Recent years have seen a shift in interest of companies from marketed/late stage assets to early/mid-stage assets to access innovation at a reasonable price



Source: EY analysis, Capital IQ. | *2022 data as of 30 November. Phase analysis based on data for 503 biopharma deals, excluding over-the-counter, animal health, generics, CRO/CDMO transactions. Megadeals, valued at greater than US\$40 billion, were also excluded from the phase analysis. If the deal involved multiple products, the most advanced product was used to characterize the deal's development stage. Numbers may not add up to 100 due to rounding.

Figure 10: Biopharma deal volume 2014-2022*, by therapeutic area focus

Biopharma M&A value trend by Top TAs (US\$b), 2014-2022

	2014	2015	2016	2017	2018	2019	2020	2021	2022*
Rare diseases	1.1	7.2	0.7	2.0	2.4	7.7	4.5	6.8	30.2
Oncology	17.9	31.4	30.7	26.7	31.9	28.0	30.7	14.5	12.9
CNS	15.4	6.8	4.0	2.2	10.2	4.0	9.3	9.7	12.5
Immunology	5.9	9.1	6.2	1.2	1.2	19.7	8.6	12.3	6.8
Blood	1.3	0.0	0.8	1.7	16.1	0.9	1.4	0.5	4.9
Infectious disease	15.4	4.5	1.6	0.8	0.3	1.1	2.3	0.2	4.3
Cardiovascular	0.5	6.6	0.2	29.4	0.1	6.8	15.2	11.2	0.6
Others	93.4	98.2	67.0	23.9	15.3	57.7	17.9	48.8	16.1
Total	151	164	111	88	77	126	90	104	88

Biopharma M&A volume trend by Top TAs, 2014-2022

	2014	2015	2016	2017	2018	2019	2020	2021	2022*
Oncology	12	15	16	12	18	13	9	15	16
Immunology	2	5	5	3	1	8	3	8	7
CNS	10	12	10	4	4	7	11	6	5
Genito-urinary	4	1	2	4	1	2	3	3	4
Rare diseases	3	5	2	9	5	7	2	5	4
Infectious disease	9	5	1	3	2	1	3	1	4
Ophthalmology	2	3	2	-	3	3	3	3	3
Cardiovascular	1	6	2	1	1	1	4	1	2
Others	64	61	51	30	31	26	29	48	30
Total	107	113	91	66	66	68	67	90	75

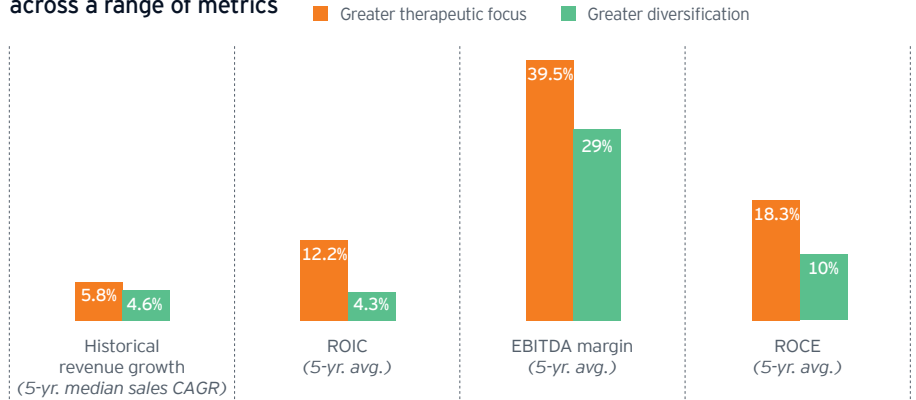
Source: EY, Capital IQ, M&A data as of 31 December, 2022. Only Biopharma deals with publicly disclosed values greater than US\$100 million were considered for this analysis. Note: 2022* represents YTD data until 30 Nov 2022. Analysis excludes mega-mergers.

Analyze what kinds of deals have worked successfully in the past

While there can be no definitive rules for executing a successful deal, EY analysis of past trends suggests that bolt-on transactions yield better results when the target company is in a therapy area adjacent to the core portfolio of the acquiring company.

These findings align with the EY analysis that success is more likely for companies that build depth and expertise in specific therapeutic areas rather than diversifying across a broad range of therapeutic fields (see Figure 11).

Figure 11: More focused companies outperform more diversified companies across a range of metrics



Source: EY, Capital IQ, Market data as of 31 October, 2022. Companies with greater therapeutic focus are defined as companies deriving greater than 50% of their revenue from one therapy area. Companies with greater diversification generates less than 50% of their revenue from a single therapy area. Based on this definition eight companies have greater therapeutic focus and 17 show greater diversification. EBITDA is earnings before interest, taxes, depreciation and amortization. ROIC, return on invested capital, calculates how effectively a company allocates capital to profitable investments or projects. ROCE, return on capital employed, indicates a financial ratio used to assess profitability and capital efficiency.



Have good processes in place to integrate new acquisitions

Successful M&A depends not only on completing the deal efficiently and cost-effectively, but on having the right teams and processes in place to achieve rapid and effective integration of the companies and teams being brought together. In general, companies should follow this five-point plan for M&A success:

1. Post-acquisition or investment, focus on protecting the “crown jewels” that will drive the future direction of the company.
2. Identify and empower the transition leader early in the diligence phase and build out a Day One readiness plan built around purpose, intent and speed. Build a mindset of continuous value creation – and flex as business and market conditions evolve.
3. Determine during the planning phase whether to fully integrate, to leave the acquired company/assets as standalone, or to take a hybrid approach. (See our guest perspective with Marianne De Backer, Head of Strategy, Business Development and Licensing, Bayer Pharmaceuticals Division, for more on this theme). This decision will be driven by multiple factors including:
 - a. The size of the acquisition.
 - b. The degree of alignment with the acquirer’s core business, people and capabilities.
 - c. The level of expectation of the target to truly transform the future trajectory of the acquirer.
4. Focus on change experience and communicate early and often to achieve buy-in to a common purpose and vision, help align the broader organizations and reduce the risk of workforce uncertainty.
5. Make optimal use of tools and technology to manage timelines, monitor work streams, and identify and deliver synergy value.



However, each deal has its own unique challenges, and this is where EY professionals that are focused on delivering the insight and guidance can help clients identify and perform due diligence on potential assets and integrate an acquisition successfully, to help optimizing the outcome of their M&A.

EY professionals have experience that extends from starting up the integration management office, through synergy identification, operating model design, change management and functional integration.

The life sciences industry has the resources, incentives and opportunities to lean into making major, transformative M&A moves again in 2023. These deals can help secure access to new innovations, close growth gaps and help secure a company’s place in a rapidly evolving health ecosystem. But companies must not lose sight of the fact that finding and acquiring the right target is only the first step; the process of M&A must be optimized end-to-end if it is to deliver the long-term results companies are seeking.

GUEST PERSPECTIVES



Marianne De Backer

MSc, PhD, MBA, Head of Strategy,
Business Development and Licensing
and Open Innovation,
Pharma, Bayer

How Bayer is partnering to drive innovation

At Bayer, partnerships are critical to our current and future success and in the last three years we have significantly increased our activities with external partners. We have acquired four companies and entered into over 50 alliances. Many of our biggest marketed brands (Eylea with Regeneron, Xarelto with Johnson & Johnson, Nubeqa with Orion) are the fruits of partnerships, and over 60 percent of our current pipeline is partnered. We embrace innovation wherever we find it, to build new spaces or strengthen our position in spaces where we already play.

I oversee Bayer's growth strategy, business development & licensing and Open Innovation, including our start-up incubators. When we look at external innovation, be it a drug or a technology, we are agnostic on what type of partnership we pursue. Depending on our strategic needs, we can pursue any type of deal, be it an option deal, an equity investment or an acquisition. Our focus is ensuring the asset can be accelerated with the highest probability of success.

For example, we took a straightforward acquisition approach with KaNDy Therapeutics, a UK-based company with a Phase III ready drug for vasomotor symptoms associated with menopause. As an established leader in the women's healthcare space, it made sense for us to simply buy and integrate the company.

We have taken a very different approach with the companies that have developed new capabilities and technology platforms to serve major unmet medical needs that cannot be addressed with existing modalities. For example, we set a goal to become leaders in cell and gene therapies. Here we needed to go further than forming a research alliance, in-licensing an asset, or building a portfolio through multiple small deals.

“

The goal of our arm's length model is to bring the best of both worlds together and accelerate programs. Having been in the industry for more than 30 years and having seen many acquisitions fail to deliver on their promise, I strongly believe in this model.

Marianne De Backer

MSc, PhD, MBA, Head of Strategy, Business Development and Licensing, and Open Innovation, Pharma, Bayer

There were clear leaders in the field, and it was critical that we brought in capabilities and knowledge to advance rapidly to the next level. We acquired Asklepios BioPharmaceutical, Inc. (AskBio), and that brought with it not just the clinical-stage assets, the technologies and the contract development and manufacturing organization (CDMO) business, but also all the talent and the expertise.

We have taken similar approaches with BlueRock Therapeutics (BlueRock), which develops iPSC-based regenerative medicine cell therapies, and for Vividion Therapeutics (Vividion), focused on chemoproteomics. These are all platform companies with capabilities we want to access. For these companies we use our “arm's length” model. We want them to retain their name and identity, keep their entrepreneurial culture, and remain in charge of their own programs. We agree on milestones to be achieved, set a three-year budget, and then establish a governance board, bringing in external experts and investors from the industry as well as senior executives from within Bayer. Cybersecurity, pharmacovigilance and of course patient safety are non-negotiable, but in general we keep governance to a minimum and enable these companies to focus on developing their platform. We aim to preserve their successful culture and not over-burden it with bureaucracy.

The goal of this model is to bring the best of both worlds – biotech and biopharma – together and accelerate programs. Having been in the industry for over 30 years and seen many acquisitions fail to deliver on their promise, I strongly believe in this model, which has enabled AskBio, BlueRock and Vividion to grow, attract new talent, and enter in turn into new partnerships.

In my first year at Bayer, I established a team focused on digital and data sciences partnerships. We seek ways to plug new technologies into existing activities: for example, our partnership with Recursion Pharmaceuticals using AI and machine learning to find new drugs against fibrosis and our work with the Stanford Center for Digital Health and Huma to decentralize clinical trial recruitment. We also consider digital technologies that can drive independent commercial value; we have teamed up with 7wireVentures to monitor a spectrum of digital health start-ups, look for potential winners, and make small bets through our equity arm, Leaps by Bayer. If something really interesting develops, we can establish a more substantial partnership.

For us, M&A will remain just one option when it comes to securing innovation. Across the industry, there has inevitably been less M&A in the past since valuations were extremely high and target companies had greater optionality because of their record levels of access to capital. Now that there has been a market correction, we are seeing more bolt-on M&As happening. For us, the decision to acquire or not depends on our strategic goal and the specifics of each potential target company.

Will joining two companies make us faster and better, should we look at option or licensing deals, or is it more appropriate to make an equity investment – or to combine equity with research, with our joint labs allowing our teams to collaborate with academia to solve problems? Ultimately, it is a question of where we want to go, and what kind of assets or solutions will help us get there. M&A and these complementary partnership alternatives all form part of a toolbox we can use to access to innovation as we continue to pursue our long-term strategic goals.

GUEST PERSPECTIVES



Lisa Huang
Principal, Blackstone

Private equity's partnership potential in life sciences R&D

At Blackstone Life Sciences (Bxls), we don't simply invest in MedTech and biopharma companies - we actively partner with them, connecting them with the capital, capabilities and insights they need to accelerate their innovations with minimal or no impact on earnings, R&D budgets or dilution.

Bxls launched almost five years ago, when Blackstone acquired Clarus Ventures - a leading global life sciences investment firm with more than a decade of experience partnering with major companies in the space. We take a flexible approach, structuring deals to enable our partners to fund their pipelines without expanding their budgets and deploying capital through various structures, including product financing, royalty monetization and debt.

With some of our biopharma and MedTech partners, we use a collaborative model, where the biopharma or MedTech continues to develop the asset, while with others, we use an ownership model, where we out-license the intellectual property and create a company around it. With our biotech partners, we provide non-dilutive capital they can use to further develop their pipelines or invest in commercial product launches.

In addition to our flexible capital at scale, we also offer our partners extensive strategic and operational capabilities in drug development, commercialization and finance. This enables us to work closely with all types of companies at various stages of their growth. Generally speaking, however, we focus on late-stage, post-proof-of-concept opportunities, prioritizing best-in-class therapies that address the underlying causes of disease and serve significant unmet patient needs. We have invested in leading therapeutic modalities - including RNA and cell therapies - and are currently very active in the oncology, cardiovascular/metabolic, CNS and immunology spaces.

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We foresee a critical window of opportunity opening between 2025 and 2030, as loss of exclusivity challenges drive high activity in M&A, collaborations, licensing and partnerships.

Lisa Huang
Principal, Blackstone

Looking ahead, we continue to follow how COVID-19 has impacted our industry and accelerated development, including decentralized clinical trials. If this pattern continues, it may translate into streamlined development processes, opening more opportunities for us to deploy capital and get products to patients more efficiently. We are also monitoring how AI and other digital technologies can expedite development times and improve chances of clinical trial success.

In the nearer term, we foresee a critical window of opportunity opening between 2025 and 2030, as loss of exclusivity challenges drive high activity in M&A, collaborations, licensing and partnerships. BXLS is well-positioned to take advantage of this headwind: not only do we have capital to deploy, but we can partner with companies to share upfront acquisition or licensing costs and/or help them fund R&D for assets they already have in-house.

These capabilities give us great confidence in the road ahead, despite recent decreases in deal values and biotech valuations, due in part to the tougher regulatory environment. Companies with transformative, first-in-class innovations that hold significant patient and market potential usually fare well regardless of the broader market environment and attract capital and buyers. We look forward to collaborating with these kinds of partners in 2023 and beyond, funding their innovation and equipping them to develop the life-saving therapies and treatments of tomorrow.



GUEST PERSPECTIVES



Heather E. Meade
Principal, Washington Council
Ernst & Young

What life science leaders should watch in a divided Washington

Regulatory and legislative changes have the potential to trigger big reactions in the US market - in some cases changing the calculus for M&A.

With Democrats controlling both Congress and the House of Representatives for the past two years, US policymakers have homed in on the life sciences industry, looking for ways to address rising costs by cracking down on anticompetitive behavior and reducing government and consumer spending on prescription drugs across the supply chain.

Democrats used their final months controlling both chambers in Congress to pass two pieces of legislation that will greatly impact the life sciences sector: the Inflation Reduction Act (IRA) and the Food and Drug Administration's User Fee Reauthorization package. On the heels of the IRA's passage, pharmaceutical companies have been quick to blame the bill's drug pricing provisions for their decision to halt certain drugs in their development pipelines. However, much remains to be seen in terms of implementation - from upcoming agency guidance to likely legal challenges.

And while some in the new Republican-controlled House have promised to repeal the IRA's Medicare drug price negotiation provisions, that, along with other partisan efforts, are extremely unlikely to pass in a divided Washington. Regulatory forces are thus likely to continue to have an outsized impact on M&A activity in the life sciences industry.

Below are four developments to watch that undoubtedly will have implications for the life sciences industry in 2023 and beyond:

1. Antitrust activity at the Federal Trade Commission (FTC) and U. S. Department of Justice (DOJ)

Since assuming office in 2021, the Biden administration has repeatedly signaled its intent to crack down on antitrust activity in the health care sector:

- ▶ In March 2021, the FTC and DOJ teamed up with state attorneys general and regulators in Canada, the European Union and the United Kingdom to launch the Multilateral Pharmaceutical Merger Task Force, which is taking a closer look at how regulators measure the impact of pharmaceutical mergers.
- ▶ In January 2022, the FTC and DOJ launched a review of merger guidelines in response to an executive order from President Biden.
- ▶ In June 2022, the FTC launched an effort to examine the impact of vertically integrated pharmacy benefit managers on drug prices and access.
- ▶ In October 2022, FTC Chair Lina Khan said the agency is “looking closely at the role of private equity” in health care.

While recent FTC and DOJ legal action in life sciences has centered around “pay-for-delay” deals or price-fixing litigation and fraud, the above suggests that Biden’s FTC and DOJ are looking more closely at M&A activity in life sciences. This additional scrutiny could lead to updated merger guidelines and/or new waves of legal action targeting M&A deals in life sciences, as we’ve already begun to see in the provider space.

2. FDA’s accelerated approval program

Over the last year, the FDA has flexed its regulatory muscle via its accelerated approval pathway – and pending bipartisan legislation could strengthen the agency’s oversight. The FDA is still dealing with the fallout of its June 2021 decision to use the accelerated approval pathway to approve the Alzheimer’s drug Aduhelm despite an advisory committee’s near

unanimous vote that clinical trials failed to show adequate efficacy. And, in October 2022, an FDA advisory committee recommended the FDA pull a preterm birth drug Makena from the market after post-market studies failed to show clinical benefit. If the FDA acts on the recommendation, Makena will become the first accelerated approval drug to be fully removed from the market.

When coupled with legislative proposals to modernize the accelerated approvals pathway such as by clarifying the agency’s authority to require post-approval studies and pull drugs from the market, these actions could have big implications for the types of drugs pharmaceutical companies invest in and acquire.

3. End of the public health emergency

While COVID-19 cases continue to rise and fall in different parts of the country, we’ve seen a notable shift at the federal level toward winding down the COVID-19 public health emergency (PHE). The PHE is currently extended through mid-January, and it’s widely believed that the Biden administration will renew it at least once more, setting up a potential end date in 2023 and the end of numerous waiver flexibilities in health care.

For the life sciences industry, the PHE ending will lead to a shift in funding for COVID-19 tests, treatments and vaccines. Currently, the federal government covers most costs for diagnostics, treatments and vaccines, and some of their marketing, but as federal funding runs out, the cost burden will shift to the commercial market. At the same time, pharmaceutical companies are re-evaluating the price of their COVID-19-related products.

With health policy changes large and small under consideration, understanding the perspective of the life sciences industry will continue to be important for both Congress and the administration through the remainder of 2022 and into next year. Industry leaders should look for opportunities to feed into the policymaking process to share with policymakers how the market can best function to better serve the needs of patients.

METHODOLOGY

Dealmaking and financing analyses

Life sciences dealmaking and financing activities were analyzed from 1 January 2014 to 30 November 2022 using data from Capital IQ, Biomedtracker and PitchBook.

M&A deals with disclosed values greater than US\$100 million were categorized according to the target's subsector (e.g., biopharma or MedTech) and by rationale as follows:

- ▶ **Asset swap:** transaction in which the companies participate as both acquirers and sellers, negotiating the exchange of assets with each other
- ▶ **Bolt-on:** small-to medium-sized acquisitions that account for less than 25% of the buyer's market capitalization
- ▶ **Financial deal:** characterization used when the acquirer is a financial buyer (e.g., private equity) outside the life sciences industry
- ▶ **Geographic expansion:** acquisitions by a life sciences company specifically designed to access capabilities in a new geography

This does not include cross-border transactions that are part of larger, transformative transactions

- ▶ **Megamergers:** acquisitions with valuations of roughly US\$40 billion (biopharma) and US\$10 billion (MedTech)
- ▶ **Transformative deals:** transaction in which the deal value is greater than 50% of the acquirer's market capitalization at the time of purchase

Acquired companies were classified by the stage and therapy area according to their lead asset, as defined by Evaluate Pharma. Unless otherwise noted, these analyses excluded deals for over-the-counter, generics or animal health products.

Firepower analysis

The EY organization defines Firepower as a company's capacity to fund transactions based on its balance sheet. It has multiple inputs, including (1) cash and equivalents; (2) debt capacity, including credit lines; and (3) market capitalizations. The following assumptions underpin the analysis:

- ▶ A company will not acquire targets that exceed 50% of its existing market capitalization.
- ▶ When a transaction results in a new company, the debt-to-equity ratio of the combined entity cannot exceed 30%.
- ▶ Equity is measured on a market value basis.
- ▶ The methodology does not calculate the ability to perform M&A via stock-for-stock transactions. However, increases in a company's stock price do increase a company's Firepower because increased equity enables companies to borrow more to finance transactions.

Firepower trends are measured across the biopharma and MedTech subsectors, as well as for individual companies. While some life sciences companies have made acquisitions that extend beyond the upper threshold defined in the Firepower methodology, the goal is to create a uniform approach to measure relative changes in Firepower.

The EY organization defines deployed Firepower as the ratio of capital spent on M&A or alliances by a company or subsector in a given period relative to the available Firepower as determined by the inputs described on the previous page. Unless otherwise noted, 30 November data was used to calculate annual Firepower results. In instances where transactions by companies in two different subsectors took place, Firepower calculations were performed for the separate entities until the close of the transaction.

The 25 biopharmas included in the analysis were:

- ▶ AbbVie Inc.
- ▶ Amgen Inc.
- ▶ Astellas Pharma
- ▶ AstraZeneca PLC
- ▶ Bayer AG
- ▶ Biogen Inc.
- ▶ Boehringer Ingelheim
- ▶ Bristol Myers Squibb Co.
- ▶ Daiichi Sankyo Co. Ltd.
- ▶ Eisai Co., Ltd.
- ▶ Eli Lilly and Company
- ▶ Gilead Sciences, Inc.
- ▶ GlaxoSmithKline PLC
- ▶ Johnson & Johnson
- ▶ Merck & Co., Inc.
- ▶ Merck KGaA, headquartered in Darmstadt, Germany
- ▶ Novartis AG
- ▶ Novo Nordisk A/S
- ▶ Otsuka Pharmaceutical Co., Ltd.
- ▶ Pfizer Inc.
- ▶ Regeneron Pharmaceuticals Inc.
- ▶ Roche Holding AG
- ▶ Sanofi
- ▶ Takeda Pharmaceutical Company Ltd.
- ▶ UCB S.A.

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How EY's Global Life Sciences Sector can help your business
As populations age and chronic diseases become commonplace, health care will take an ever larger share of GDP. Scientific progress, augmented intelligence and a more empowered patient are driving changes in the delivery of health care to a personalized experience that demands health outcomes as the core metric. This is causing a power shift among traditional stakeholder groups, with new entrants (often not driven by profit) disrupting incumbents. Innovation, productivity and access to patients remain the industry's biggest challenges. These trends challenge the capital strategy of every link in the life sciences value chain, from R&D and product supply to product launch and patient-centric operating models.

Our Global Life Sciences Sector brings together a worldwide network of 23,000 sector-focused professionals to anticipate trends, identify their implications and help our clients create competitive advantage. We can help you navigate your way forward and achieve sustainable success in the new health-outcomes-driven ecosystem.

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