White Paper

A Big Deal: Strategic Rejuvenation for Post-Pandemic Realities

The critical role of deal-making in sustaining biopharma's momentum

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Introduction

Mergers and acquisitions (M&A) have been an essential part of the biopharmaceutical business model for many decades. As a capital-intensive, innovation-driven industry, biopharmaceutical companies have pursued M&A for a variety of reasons, ranging from capturing cost synergies and replenishing R&D pipelines to the expansion into new therapy areas or geographies. Collectively, the industry spent more than $1 trillion on M&A transactions over the past 5 years alone.[1]

Between the mid-1990s and early 2010s, when the industry was largely reliant on primary care products, several of them blockbusters, mega-mergers led to significant industry consolidation in response to many revenue drivers facing loss of exclusivity, with the patent cliff of 2011/12 a key defining event. Those mergers typically focused on cost synergies and sustaining growth by adding revenue generating, protected in-line brands to stem the top-line erosion caused by maturing portfolios.

Since then, the biopharmaceutical industry transitioned from tackling mass-market primary care conditions, such as cardiovascular, GI or respiratory, that affect large patient populations often in the order of hundreds of millions, to a specialty model with focus on much smaller patient segments in therapy areas such as oncology, immunology or rare diseases. And with it, the focus of M&A changed, too, as scale and cost synergies matter less. Instead, success has become increasingly dependent on access to innovation, whether novel molecular assets or transformative technologies, to create new growth platforms. Consequently, M&A activity has shifted towards bolt-on acquisitions to source external innovation.

As we are emerging from the COVID-19 pandemic, the biopharmaceutical industry must adapt to new realities created by the disruption of legacy business models, with re-set customer expectations and a redefined competitive landscape with new types of players, while at the same time still facing 'old' challenges, such as the next patent cliff through the mid-2020s.

M&A will play an important role in bringing about the necessary strategic rejuvenation of biopharmaceutical companies. However, pure M&A alone, in which assets or companies change ownership, is not the answer to all of the industry's challenges.

There are several reasons for this. Firstly, not all innovation is for sale, e.g. technology platforms, as opposed to individual molecular assets. Secondly, large biopharma companies are not necessarily the best owner for sustaining cutting-edge capabilities which benefit from a nimble start-up culture that is difficult to replicate within a large corporate organisation. Thirdly, outright ownership of de-risked assets in a highly competitive environment is typically very expensive, whereas partnerships can be structured in attractive ways, e.g. deferring the majority of payments until milestones are achieved to mitigate risk. This makes strategic collaborations and alliances increasingly critical for accessing innovation and as a means to assemble, or participate in, multi-stakeholder networks.

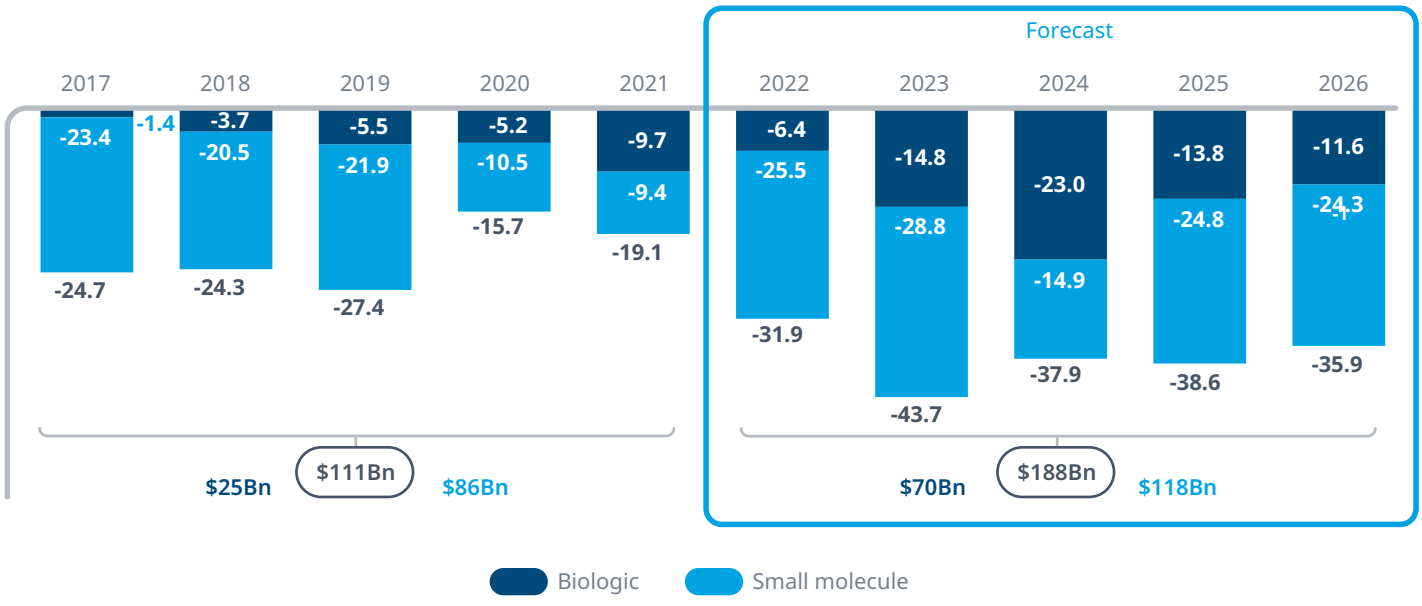
Companies therefore will need to judiciously embrace the full spectrum of deal-making options, including M&A and partnerships, to thrive in the post-pandemic world.

The strategic imperative for biopharma deal-making

The biopharmaceutical industry is facing serious headwinds in the near- to medium-term future that challenge the current performance trajectory of many companies:

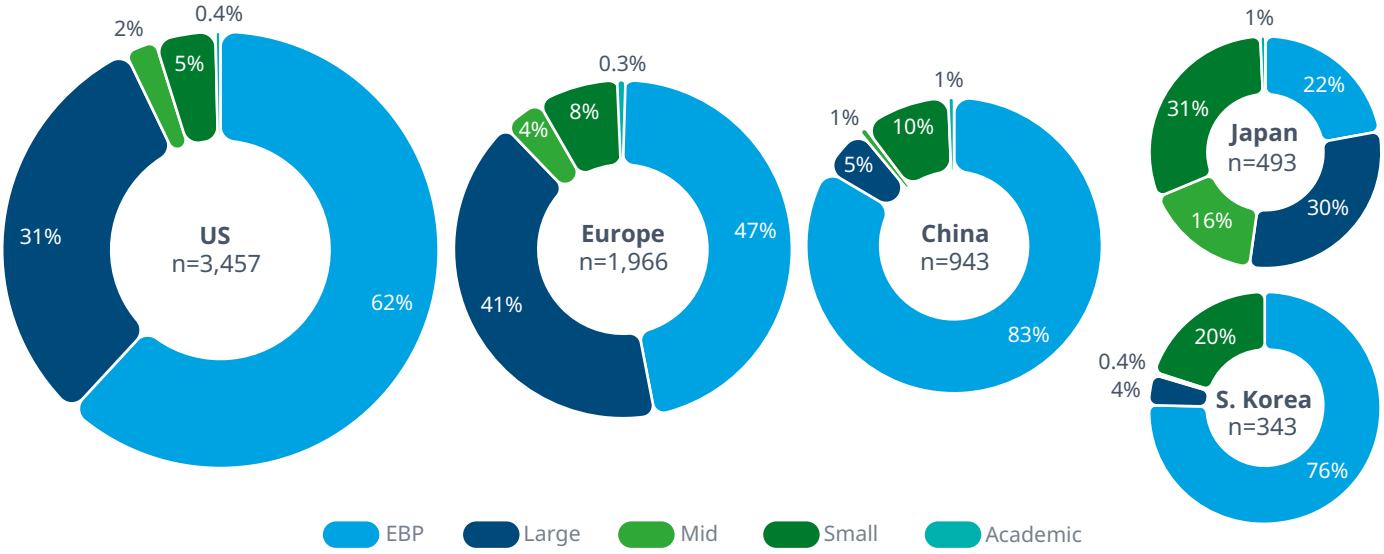
- **Loss of exclusivity:** Over the next 5 years, protected brands losing exclusivity (LoE) will result in $188 billion of lost revenue in the developed markets, an increase of 69% from the LoE impact seen over the past 5 years. Biosimilars are a key driver of this increase, with the impact of biologics LoEs nearly tripling from $25 billion to $70 billion of lost revenue between the two time periods[2] (see Figure 1). Unlike when the industry was facing the primary care patent cliff in 2011/12, mega-mergers in pursuit of cost synergies will do little to alleviate the LoE impact of the 2020s. With the industry predominantly focused on specialty care today, stepping up innovation, both internally and via external sources, is the only answer.
- **Ongoing COVID-19 impact:** Health systems continue to be both financially and operationally constrained as a result of the pandemic, having to operate under severe budget pressures while still struggling to clear patient backlogs. This creates an unforgiving environment for product launches because the dynamic market (of new and switch patients), which is vital for driving launch uptake, all but collapsed during the pandemic and it has still not fully recovered. As a result, peri-pandemic launches significantly underperform against pre-pandemic benchmarks across key markets (i.e. US, EU4/UK, Japan and China), with average country trajectories of primary care and specialty launches depressed by 39%–63% and 28%–68%, respectively.[3] Worryingly, that performance gap shows no signs of closing, and it further exacerbates the pressure on companies that must replace revenue lost due to patent expiries.

Figure 1: Developed markets* impact of brand losses of exclusivity, 2017–2026 (US$Bn)



* Includes US, Canada, EU4/UK, Japan, South Korea, Australia
Source: IQVIA Market Prognosis, Sep 2021; The Global Use of Medicines 2022: Outlook to 2026, IQVIA Institute, Jan 2022.

Figure 2: Share of pipeline candidates by company segment and HQ location



Source: IQVIA Pipeline Intelligence, Dec 2021; Global trends in R&D through 2021, IQVIA Institute, Feb 2022.

- **P&L squeeze:** The biopharma industry P&L is under pressure, with R&D cost and COGS rising faster than sales, at 5-year CAGR (2016-21) of 8.1% and 8.9% vs. 6.9%, respectively, for the top 15 big pharma companies.[4] This trend erodes companies' profitability and challenges the sustainability of the legacy business model. Disconcertingly, R&D spend effectiveness remains at historically low levels.[5]

To sustain their performance trajectories, and support their valuations, biopharmaceutical companies must unlock new growth momentum through innovation.

Today, the vast majority of innovation originates from outside large and mid-size companies. Specifically, emerging biopharma companies (EBPs)[6] are the key drivers of biomedical innovation in most regions, accounting for 65% of all clinical-stage candidates in the global industry pipeline in 2021[5] (see Figure 2). A new source of innovation coming to the fore, China-headquartered companies now represent 17% of the global EBP pipeline, up from 6% just 5 years ago.[5] Therefore, the ability to harness external sources of innovation is critical for the industry's sustained, future success.

In addition to addressing their innovation challenge, biopharmaceutical companies must also position themselves for post-pandemic competitive realities, as the healthcare landscape is becoming increasingly diverse (see Figure 3).

New types of players, and models, have emerged during the pandemic, including, for example, novel technology platforms such as mRNA that challenge the traditional R&D paradigm; digital players that leverage expertise in consumer engagement and analytics or logistics platforms to successfully enter healthcare by creating superior patient experiences and outcomes; diagnostics companies seeking to enable personalised and precision medicine; meanwhile low-cost fast followers, e.g. EQRx or Chinese players, aim to disrupt the market

Figure 3: Post-pandemic competitive realities — new types of players

Sources: IQVIA European Thought Leadership.

by competing on price with protected, comparable therapies against established category leaders, for example in the area of immune checkpoint inhibitors.[7]

Incumbent biopharmaceutical companies will need to make strategic choices about requisite, critical capabilities for this new competitive reality and whether to build, acquire or access them via partnerships. For many of the future-critical capabilities, biopharma is not the natural owner, e.g. big data, digital health, advanced analytics or next-generation diagnostics. Besides, cutting-edge capabilities often evolve so fast that only a partnership model can move with the pace of innovation. We therefore expect collaborations to be the main focus for addressing many capability gaps, with very selective and targeted M&A potentially playing a role here, too.

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Against this backdrop of the biopharmaceutical industry's major challenges, the importance of deal-making in overcoming these cannot be overstated. Specifically, deal-making addresses four strategic priorities:

1. **Sourcing of innovation:** Harnessing external sources of innovation has been a long-standing, major motivation for biopharma deal-making to replenish pipelines and portfolios. In fact, many of today's most successful products were sourced from outside the commercialising company, e.g. Humira or Keytruda via M&A, Dupixent or Comirnaty via partnerships. As our analysis shows, the originator was different from the launching entity for 53% of all New Active Substances launched in the US over the past decade.

2. **Access to novel capabilities:** Deal-making is critical for gaining access to cutting-edge capabilities, for example mRNA technology, as Sanofi did with its acquisition of Translate Bio[8]; gene therapies, e.g. the acquisition of Spark Therapeutics by Roche[9], or Ask Bio by Bayer[10]; AI-powered drug discovery platforms, e.g. Exscientia's partnerships with several big pharma companies including Bayer, BMS, Roche, Sanofi[11]; or digital health, e.g. Sanofi's collaboration with DarioHealth to advance chronic disease management[12], or AstraZeneca investing in Huma to develop patient companion apps.[13]

3. **Sharpening strategic focus:** Deal-making also plays a key role in realigning a company's portfolio, especially when strategic priorities change, for example via divestment of non-core assets or businesses to a better owner, as Novartis is currently exploring for its Sandoz unit[14], or via spin-offs, e.g. Pfizer spinning off its Upjohn business of solid generics and off-patent brands and combining it with Mylan to form Viatris.[15]

4. **Fundamental transformation:** Deal-making, and M&A in particular, enables companies to fundamentally reposition themselves. For example, European mid-size company Almirall exited respiratory via divestment of its related franchise to AstraZeneca while acquiring Allergan's medical dermatology portfolio and the US dermatology specialist Aqua, followed by licensing the European rights to Dermira's lebrikizumab for eczema, thereby becoming a dermatology-focussed company with a US presence;[16] or the large-scale acquisitions of Flatiron Health and Foundation Medicine by Roche to establish itself as a leader in personalised healthcare.[17,18]

As biopharmaceutical companies look to the post-pandemic future, the strategic imperative for deal-making is indisputable.

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The state of biopharma deal-making

In 2021, overall publicly disclosed activity across different life sciences deal types dropped by 3% vs. 2020 volumes, as tracked by the IQVIA PharmaDeals database.[1] Excluding COVID-19 related transactions from the last two years, total deal volumes in 2021 were actually 9% above those in 2020 as well as 2019 pre-pandemic volumes, indicating a return to a non-COVID focus. The return to pre-pandemic patterns can also be observed in the volume of R&D collaborations, which declined from a COVID-induced spike in 2020 to typical levels seen in the years preceding the pandemic (see Figure 4).

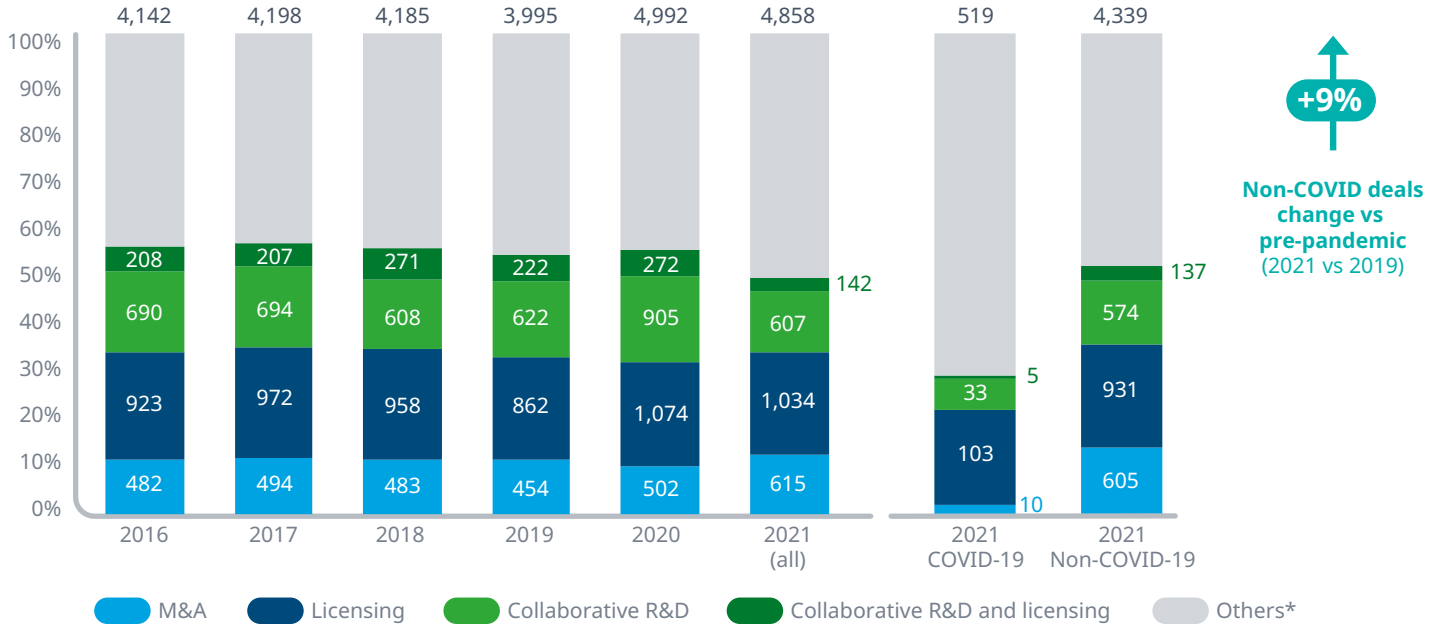
M&A deal activity in 2021, including divestments, continued to increase for the second year in a row, with a 24% year-on-year rise in volume, while aggregate total M&A deal value bounced back by 44% vs. 2020 to $255 billion. However, this is still below the recent high of nearly $300 billion of aggregate M&A transaction value reached in 2019. Importantly, mean deal value only increased modestly by 11% from $880 million in 2020 to $975 million in 2021 (see Fgure 5).

Mega-mergers were absent in 2021, even the non-synergy focussed, transformative variety of mega-deals that would instantly create critical mass in a new growth platform, e.g. by adding a sizable, rare disease franchise, as AstraZeneca did with Alexion in 2020.[19] Instead, companies preferred smaller, more targeted and thus less disruptive bolt-on acquisitions, which accounted for over 80% of total M&A volume in 2021.

DEAL FOCUS: WHAT IS HOT?

Product-related transactions across different deal types continue to be dominated by oncology, representing 40% of all new product-focused deals signed in 2021, a reflection of oncology remaining a hotbed of innovation in which many companies want to have a stake. This was followed by infectious diseases and CNS at 17% and 16% share of deals, respectively.

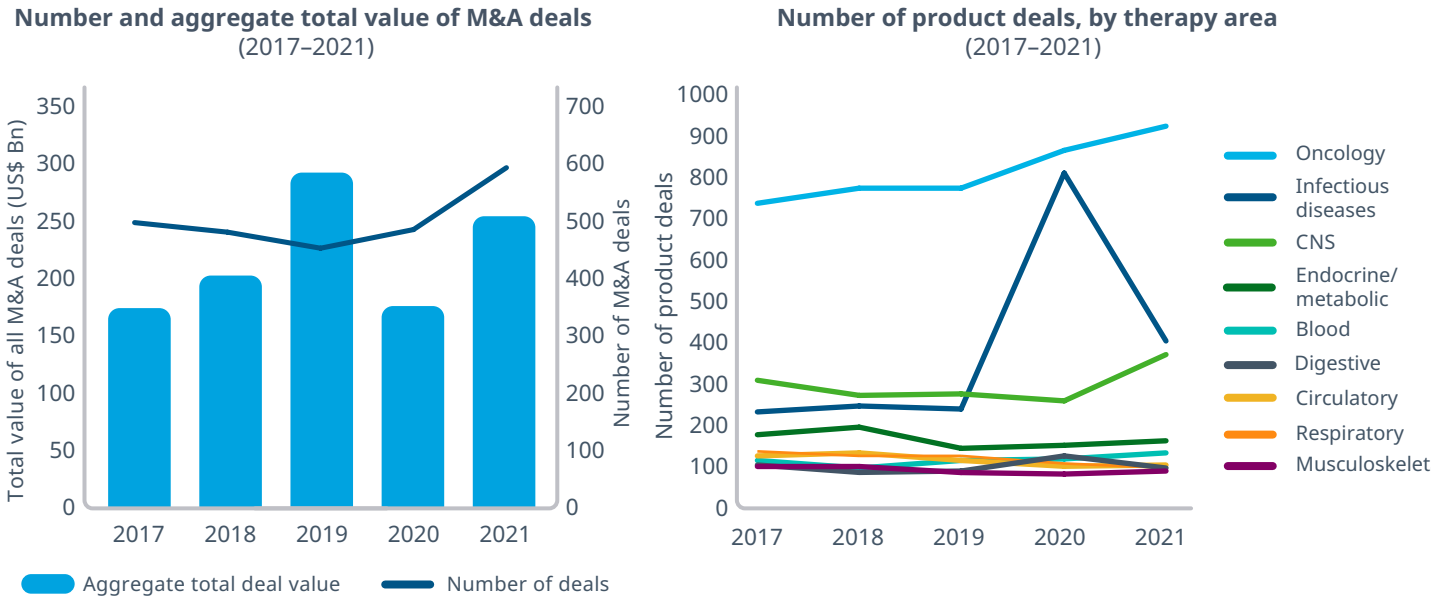
Figure 4: Number of life sciences deals, total and by type, 2016–2021



* Includes JVs, marketing alliances, distribution, research funding, clinical collaborations, technology access, contract manufacturing, contract research (not exhaustive)

Source: IQVIA PharmaDeals, Dec 2021; Global trends in R&D through 2021, IQVIA Institute, Feb 2022.

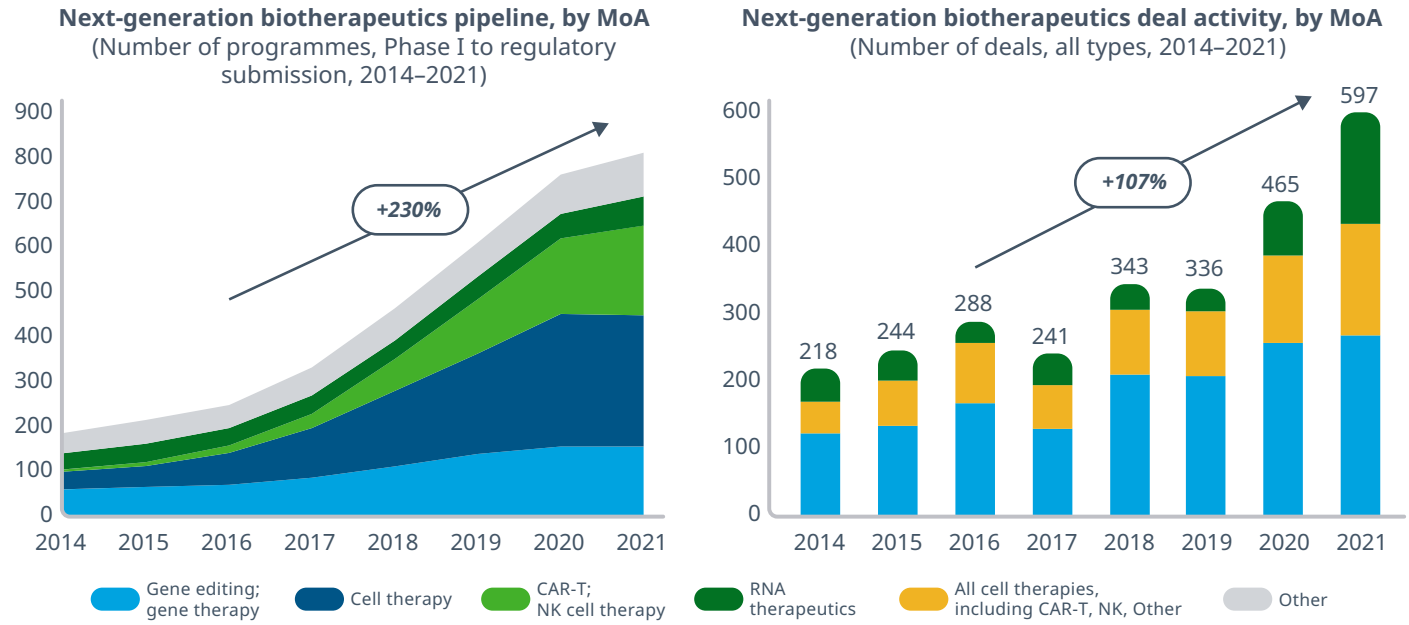
Figure 5: Deal-making landscape



Source: IQVIA PharmaDeals, Review of 2021

Infectious diseases retreated from their COVID-driven 2020 peak, but their absolute deal volume stayed above 2019 levels, while CNS saw a noticeable uptick in deal activity as an area of high unmet need with promising long-term potential, e.g. in Alzheimer's, Parkinson's, other neurodegenerative, neuromuscular or mental health conditions, and thus attracting many companies (see Figure 5).

Figure 6: Next-generation biotherapeutics are surging into focus



Source: IQVIA Pipeline Intelligence, Dec 2021; IQVIA PharmaDeals, Dec 2021; IQVIA European Thought Leadership analysis.

Next-generation biotherapeutics, including cell and gene therapies, gene editing, RNA- and DNA-based therapeutics and other novel modalities, represent the biomedical innovation frontier.[20] The phenomenal success of the development of COVID-19 vaccines in record time has demonstrated the transformative power of novel technology platforms, in particular mRNA. Over the past 5 years, the clinical-stage pipeline for next-generation biotherapeutics has more than tripled to just over 800 therapies in 2021[5], with emerging biopharma companies accounting for over 90% of that pipeline.[21] During the same time period, deal activity in this area has more than doubled across all deal types, with a pronounced surge in deals focused on RNA-therapeutics in both 2020 and 2021 (see Figure 6).

Digital transformation is a strategic priority for many biopharma companies for which they increasingly deploy a wide range of deal-making approaches to further their digital agenda. Collaborative agreements and technology licensing play a key role, alongside some outright acquisitions, to access cutting edge, digital capabilities. Many companies are also setting up accelerators and provide venture funding to embed themselves in the digital health start-up ecosystem. Through their digital investments, prolific deal-makers assemble a network of capabilities across data, analytics and applications, to boost their biomedical innovation through deeper, novel insight, unlock operational efficiencies and reimagine customer and patient engagement for a superior experience and better clinical outcomes.

Looking ahead, by the end of 2022 we expect the top 20 large-cap pharma companies to have accumulated a formidable war chest of well over $500 billion in cash for potential deployment in deal-making.

FAVOURABLE FUNDAMENTALS SUPPORT DEAL-MAKING MOMENTUM

Looking ahead, by the end of 2022 we expect the top 20 large-cap pharma companies to have accumulated a formidable war chest of well over $500 billion in cash for potential deployment in deal-making, which might even be extended to over $1.5 trillion in firepower through leverage. This soaring cash position is fuelled by a number of sources, for example, the extraordinary revenue generated from COVID vaccines and treatments for Pfizer, Moderna and Merck; one-off divestments, such as Novartis selling its stake in Roche; or established, highly cash-generative mega-franchises, e.g. AbbVie's Humira, Merck's Keytruda, BMS's Revlimid or BMS/ Pfizer's Eliquis.

The result is an embarrassment of riches as companies will be under pressure to find value-creating investment opportunities which, given the scale of available funds, is far from straightforward. While returning value to shareholders via buybacks or dividends may appeal as a low-risk option, this would do nothing to strategically position companies for future success. Hence, we should expect to see increasing deal-making activity going forward.

Beyond the traditional biopharma deal-makers, over the past few years private equity (PE) investors have shown increasing interest in life sciences. For example, in 2017 CVC acquired the women's health portfolio from Teva to create new company Theramex, which they have now sold to a consortium comprising PE firms Carlyle and PAI Partners[22]; CVC also acquired a controlling stake in Recordati[23]; Advent was bidding for rare disease company Swedish Orphan Biovitrum, which was blocked by AstraZeneca[24]; Permira bought CNS-specialist Neuraxpharm from Apax Partners[25]; or the reported interest of Blackstone and Carlyle in joining forces for a potential, large-scale $25 billion bid for Sandoz[26]. With abundant dry powder at their disposal, and a proven willingness to buy and build businesses, private equity investors are likely to become even more active in life sciences deal-making.

At the same time, we are beginning to see the tide turn on what used to be entirely a seller's market in recent years. Valuations of assets are coming down from the exorbitant heights seen in early 2021 that were propelled by an abundance of capital, accessible, for example, via VC funding, IPOs or the more recent option of special purpose acquisition companies (SPACs). As such, emerging biopharma companies faced little urgency to seek deals with larger pharmaceutical companies, while the latter were competing fiercely for access to innovative assets or novel technology platforms. Unsurprisingly, this resulted in deal premiums often exceeding 100% for companies active in sought-after areas, e.g. next-generation biotherapeutics, oncology or rare diseases.

However, over the second half of 2021 biotech stocks took a sharp downward turn, leaving many companies that went public last year trade below their IPO price today[27] and forcing investors to recalibrate expectations. Continued challenges in the public markets also make the SPAC route less attractive, which has witnessed a number of high-profile terminations[28] (see Figure 7).

As discipline returns to the markets, asset prices will no longer be detached from hitting development milestones and producing strong clinical data. Underlying pipeline fundamentals will drive valuations of emerging biopharma companies once again. For some, this means a less certain path to new funding and may force them to consider partnering with or selling to pharmaceutical companies. In any case, the return to fair value across the sector, including quality assets, bodes well for future deal-making momentum.

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Figure 7: Favourable fundamentals support deal-making momentum

Pharma's soaring war chest...

	*Example sources of cash**	
COVID vaccines and treatments	• Pfizer/BioNTech: Cominarty	$30+Bn
	• Pfizer: Paxlovid	$24+Bn
	• Moderna: Spikevax	$20+Bn
	• Merck: Lagevrio	$7+Bn
One-off divestments	• Novartis: sold stake in Roche	$20Bn
	• Novartis: Sandoz potential sale	$25+Bn
	• GSK-Pfizer Consumer Health JV spin-off, to demerge as Haleon	$10bn, plus equity stake
Established mega-franchises	• AbbVie: Humira	$20+Bn
	• Merck: Keytruda	$20+Bn
	• BMS: Revlimid	$13+Bn
	• BMS/Pfizer: Eliquis	$11+Bn

Top 20 pharma: >$500Bn cash position by end of 2022

...meets increasingly motivated sellers

80% of **2021 biotech IPOs** trading **below their offering price**

-22% **average drop from offering price** for **biotech IPOs** in 2021

-51% **drop** of **XBI biotech index** from 2021peak to 2022 trough

-58% **drop of De-SPAC index** from 2021 peak to 2022 trough

*Product sales figures are 2022 estimates

Sources: Company reports, analyst comments, publicly available financial data; IQVIA European Thought Leadership analysis.

How to become a successful deal-maker

As many companies recognise and act on the strategic imperative for deal-making, competition continues to be intense. Acquirers, or the investing entity in the case of licensing or collaboration agreements, therefore, face several challenges to compete effectively in such an environment:

- How to become an agile deal-maker and achieve a continuous state of readiness to spot opportunities early on as they emerge and to move fast to seize them?
- How to 'punch above your weight' in fiercely competitive areas, especially as a mid-size or small player with limited firepower?
- How to improve your odds by building a reputation as a preferred partner or acquirer that others seek out?
- How to avoid overpaying and thereby destroying realisable future value during times of market exuberance?

To overcome those challenges and compete effectively, leading deal-makers focus on five critical success factors (see Figure 8):

1. **Strategic clarity:** Which business priorities will deal-making address and how? This provides the foundation to inform opportunity identification and prioritisation and ensures relevance and the strategic fit of deals to maximise value for the business. Having a clear understanding of the sources of a deal's value also acts as a safeguard against allowing a company to be drawn into an endless bidding war.

2. **An efficient and disciplined process** to identify and assess value-creating targets for acquisitions, licensing and partnering, including horizon scanning for early opportunities, integrated scientific and commercial due diligence for robust prioritisation and valuation, to feed a continuous opportunity pipeline. It ensures early identification and shortlisting of potential targets, creates focus and internal alignment, and secures executive sponsorship and sign-off on negotiation boundaries well before a target is approached.

3. **Cultivating external networks** of a wide range of partners, such as service and solutions providers with unique domain expertise, e.g. scientific, commercial, financial or legal, to rapidly tap into during the deal-making process; academia, the start-up community and financial institutions, e.g. PE investors, for early opportunity scouting.

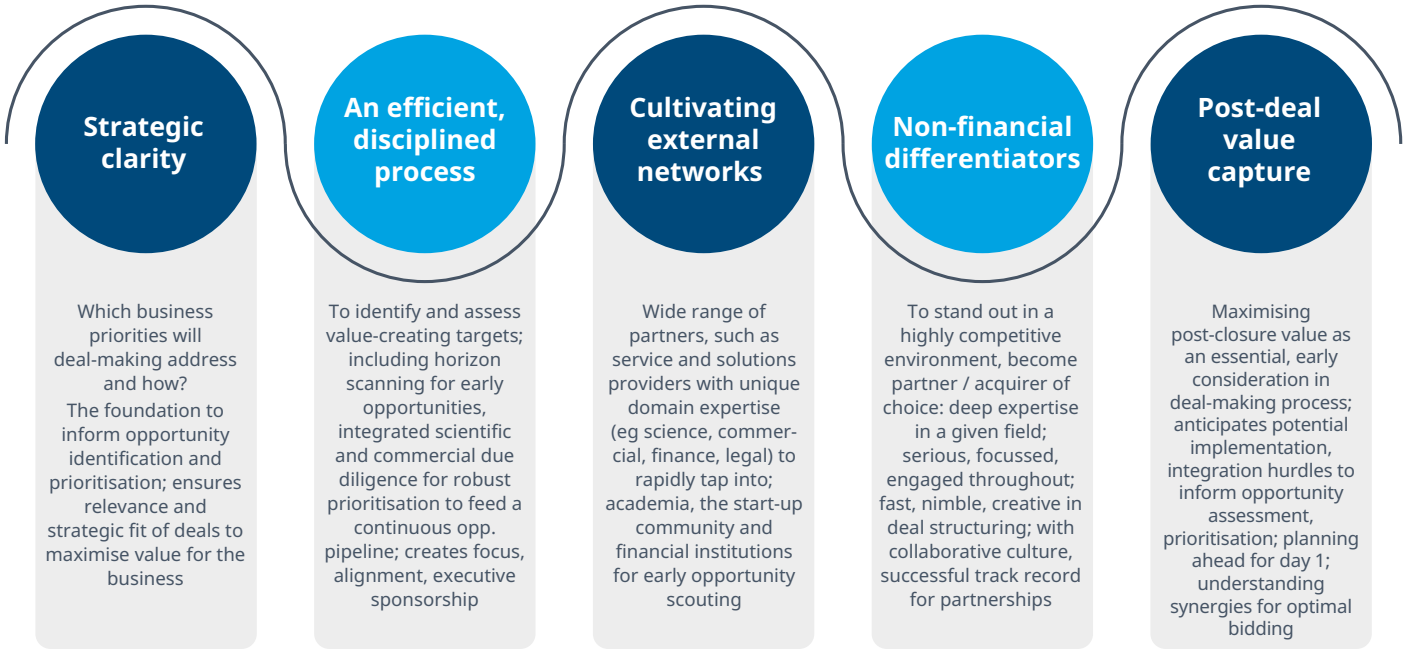
4. **Non-financial differentiators:** In a highly competitive environment, becoming a partner or acquirer of choice can markedly improve the odds of winning. For example, by establishing deep expertise in a given field; approaching targets early, being serious, focused and engaged throughout the deal process; being fast, nimble and showing creativity, e.g. in deal structuring; or by building a collaborative culture and successful track record for making partnerships work.

5. **Post-deal value capture:** How to realise and maximise post-closure value must be an essential and early consideration in the deal-making process. Leading deal-makers anticipate and evaluate potential implementation or integration hurdles to inform opportunity assessment and prioritisation, and they plan ahead for day 1 and beyond. A robust understanding of post-deal sources of value also provides them with an additional lever during competitive bidding, e.g. pricing in (some of) the synergy potential to make the winning offer.

In our extensive work of supporting companies in deal-making, we have observed the following best practice examples.

Leading deal-makers are proactive and focused, they set out by identifying a concrete list of 5–10 targets very early on, well before any external M&A activity is initiated. Subsequent outreach to targets typically starts 8–12 months before a deal is struck and often

Figure 8: Five critical success factors for winning deal-makers



Sources: IQVIA European Thought Leadership.

begins as a partnership which can rapidly turn into an acquisition. Speed is of the essence. Being the first to bid significantly increases the odds of being the one to close the deal, because competition is usually lower than expected when the bidding party demonstrates clear interest and sustained commitment. Momentum for progressing a transaction is high: 1 month for extending a non-binding offer; 1 month to close the deal.

To be able to move at such a fast pace, leading deal-makers ensure internal alignment and they secure executive sponsorship and approval for pursuing an opportunity early on, including the red lines for negotiation flexibility, for example, how much of the synergy value to share to secure the winning bid. Specifics may vary by company and depend on where responsibility for deal-making resides, e.g. with the CEO, CFO or elsewhere in the corporate hierarchy.

Clearly, successful deal-making requires much more than simply having deep pockets.

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Outlook and conclusion

As the biopharmaceutical industry emerges from the COVID-19 pandemic to face new competitive realities, deal-making will play a crucial role in companies' strategic rejuvenation.

In an increasingly competitive environment, sharpening focus will become ever more important. We should therefore expect to see more divestment of non-core assets to realign portfolios, which will also free up cash for reinvestment in strategic areas. Divestment opportunities in turn will provide fertile ground for private equity investors to further expand their role in life sciences deal making.

While we expect M&A deal activity to increase, mega-mergers are likely to remain the exception, given the financial and integration risks involved. Instead, M&A will continue to focus on targeted, less disruptive bolt-on acquisitions to source external innovation for closing companies' growth gaps and maintaining their momentum.

At the same time, the return of greater market discipline will steer the pipelines of emerging biopharma companies towards higher quality assets that offer a clear, differentiated value proposition, and it will act as a brake on an indiscriminate gold rush into overheated areas.

However, the rise of strategic collaborations and alliances will become the true hallmark of post-pandemic deal-making for gaining access to disruptive technology platforms and novel capabilities.

Only those biopharmaceutical companies that emphatically embrace the full spectrum of deal-making options, spanning M&A, licensing, collaborations and partnerships, will position themselves to thrive in the post-pandemic world.

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