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Biopharma Dealmaking and Commercialization Readiness

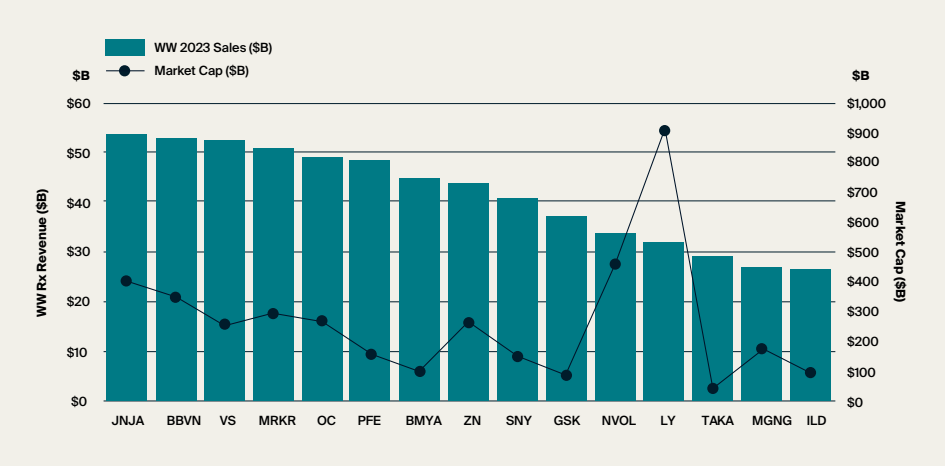
Time for a rethink?

A critical juncture for the biopharma industry

With the top 10 global pharma companies now only responsible for <5% of the industry pipeline, we know that biotech innovation has driven the growth and transformation of the pharma industry. Without biotech, pharma might never have moved beyond small molecules.[1]

Despite this, the biopharma industry is at a critical juncture, necessitating a reassessment of traditional approaches to commercialization and partnerships – **while the number of 'sellers' has increased exponentially, the number of 'buyers' has remained more or less the same** *[figure 1]*.

Figure 1
Top 15 Large Pharma – WW 2023 Rx Sales ($B) vs Market Cap ($B)

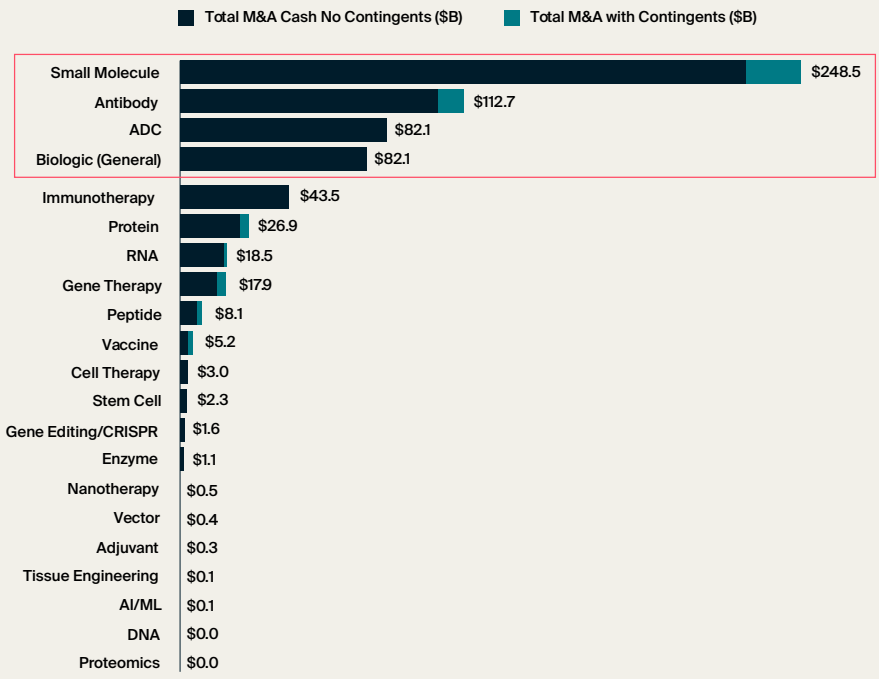


Source: Evaluate Pharma, marketwatch.com – market cap as of 03-Sep-2024

1. Mortimer R, et al. Scientific American. 2017. https://www.scientificamerican.com/blog/guest-blog/will-ldquo-biosimilar-rdquo-medications-reduce-the-cost-of-biologic-drugs/ Accessed October 30, 2024.

Today's reality is that biotechs are advancing many complex and exciting new platforms but pharma for the most part is buying only what has proven to work commercially *[figure 2].*

Figure 2
M&A total volume, top biopharma modalities - 2019-2024 YTD



Source: DealForma and Stifel analysis. Biopharmaceutical Sector Weekly Update – Jul 15, 2024: Stifel Healthcare

Creating a great product alone is insufficient to improve patients' lives and maximize value; the product must also be effectively commercialized. This paper explores important aspects of biotech commercialization, addressing prevalent myths and realities surrounding unpartnered Phase 3 assets, the likelihood of biotechs securing pharma deals, and the preparedness of biotechs attempting self-commercialization.

Common myths

01

Myth: Biotechs should not attempt commercialization because large pharma has comprehensive capabilities.

Reality: The commercial environment is rapidly evolving, particularly in the US. Breakthrough products, especially those based on complex platforms, often require commercial innovation.

However, if commercialization depended solely on big pharma, companies like Genentech, Regeneron, and Vertex would not have achieved their current success. These companies have thrived by embracing commercialization and developing innovative strategies to bring their products to market.

02

Myth: Unpartnered Phase 3 assets are either ultra-high risk or of poor quality.

Reality: Pharma diligence is not flawless, especially when assessing commercial potential. High-quality and differentiated assets often remain unpartnered because they address markets perceived as insufficiently large for pharma investment.

Despite the significant potential of advanced therapy platforms, many large pharma companies perceive these platforms as commercially unvalidated, despite promising clinical data.

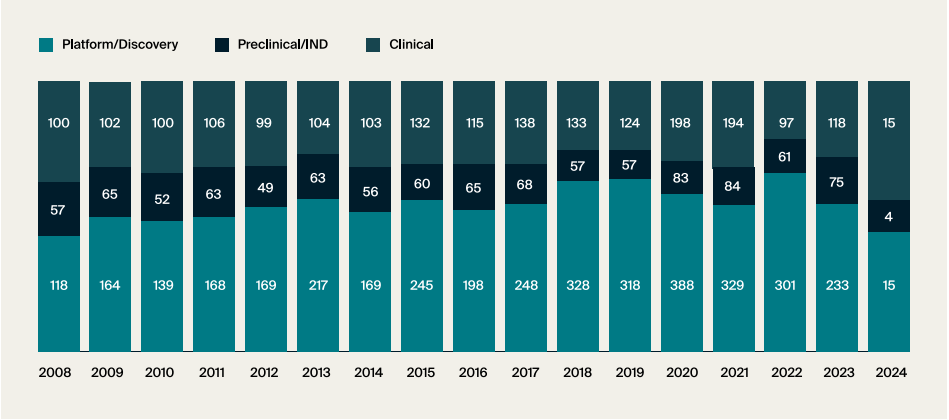
Odds of securing pharma deals

What are the odds of a biotech securing a pharma deal at Phase 3? It's true that the odds are significantly lower than the odds of regulatory approval. In 2023, only 60 out of 658 unpartnered biotech assets in Phase 3 development underwent deals, representing just 9.1% of the Phase 3 pipeline. In contrast, the probability of technical and regulatory success is much higher, with 50% at Phase 3 and 94% once filed.

This disparity highlights the challenges biotechs face in attracting pharma partners. While achieving proof of concept it only addresses clinical development as opposed to commercial risk. Pharma companies are increasingly selective in their partnerships, seeking assets that align with their strategic priorities and commercial goals. This selectivity means that many high-quality assets remain unpartnered, despite their clinical promise.

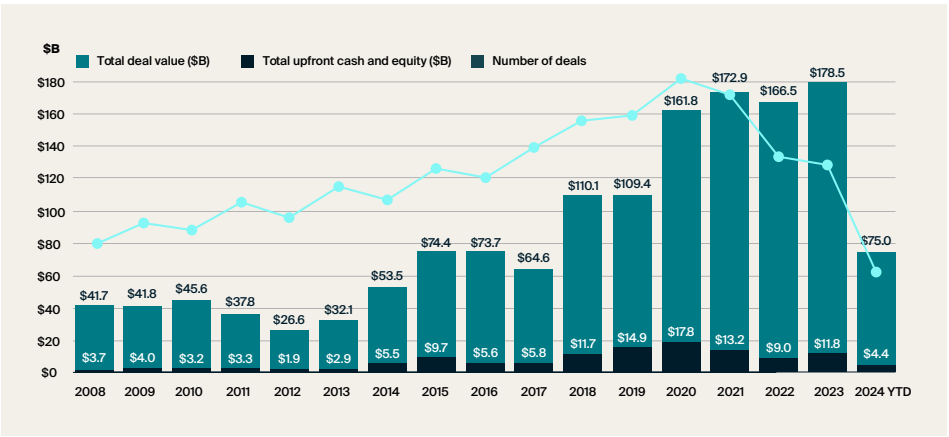
Deals are done across all stages of the lifecycle, but represent only a handful of many thousands of biotechs seeking pharma partnerships *[figure 3]*. Paradoxically, deal numbers and values across all stages are trending down *[figure 4]*

Figure 3
Number of biopharma R&D stage licensing deals by stage of development of the project 2008 to 2024 YTD



Source: DealForma, Biopharmaceutical Sector Weekly Update – Jan 29, 2024: Stifel Healthcare

Figure 4
Biopharma industry R&D stage licensing statistics, 2008 to 2024 YTD ($ billions)



Source: DealForma and Stifel analysis. Biopharmaceutical Sector Weekly Update – July 15, 2024: Stifel Healthcare

Key challenges for biotech self-commercialization

What are the key challenges and hurdles for biotechs attempting to self-commercialize their products? In most cases, there are a number of structural and strategic limitations. Here, we have summarized the ones we most commonly encounter.

01

Unpreparedness for commercialization

The transition from clinical development to commercialization can be fraught with challenges. Founded and led by scientists, many biotechs underestimate and are unprepared for the stark complexities of this transition – lacking the necessary infrastructure, expertise, commercial culture, and strategic approach to successfully launch and market their products.

02

Investor pressures/ preferences

Investors in biotech companies often prioritize rapid exits based on Proof of Concept (PoC) data over long-term company building. This preference can conflict with the need for sustained investment in commercialization efforts, again leading to under preparedness and increased risk of failure.

03

Complexity of advanced therapy platforms

Advanced therapy platforms such as autologous cell therapy and virally-delivered gene therapies present unique commercialization challenges. These complex platforms often require innovative commercial strategies that many biotechs are ill-equipped to develop and execute.

04

Development strategy

Traditional development strategies in biotech are typically milestone-driven, focusing on clinical endpoints rather than commercial viability. This approach can lead to a misalignment between clinical success and commercial readiness.

> *Too many biotech assets for sale may be clinically de-risked but are viewed by pharma as commercially challenged.*

Ed Saltzman

Looking deeper at commercialization unpreparedness

The reality is that most biotechs are significantly unprepared for what successful commercialization entails, often lacking a commercial culture and the necessary infrastructure to support a successful product launch. Many biotech firms are founded and led by academic scientists who naturally focus on clinical development rather than commercial strategy. These companies therefore lack the commercial and operational experience in their C-suites and boards to navigate the commercial path to success.

When biotechs do attempt to go commercial, they frequently fail due to inadequate preparation. They are not built or staffed for commercialization, and by the time their leadership recognizes and accepts the need for a commercial strategy, it is usually too late to turn things around. This lack of preparedness can lead to a destruction of shareholder value, with average stock prices typically peaking 2 weeks post approval and then dropping by an average of 50% more extending out 6 months. Even more concerning is that few of these companies recover any of this lost value over time.

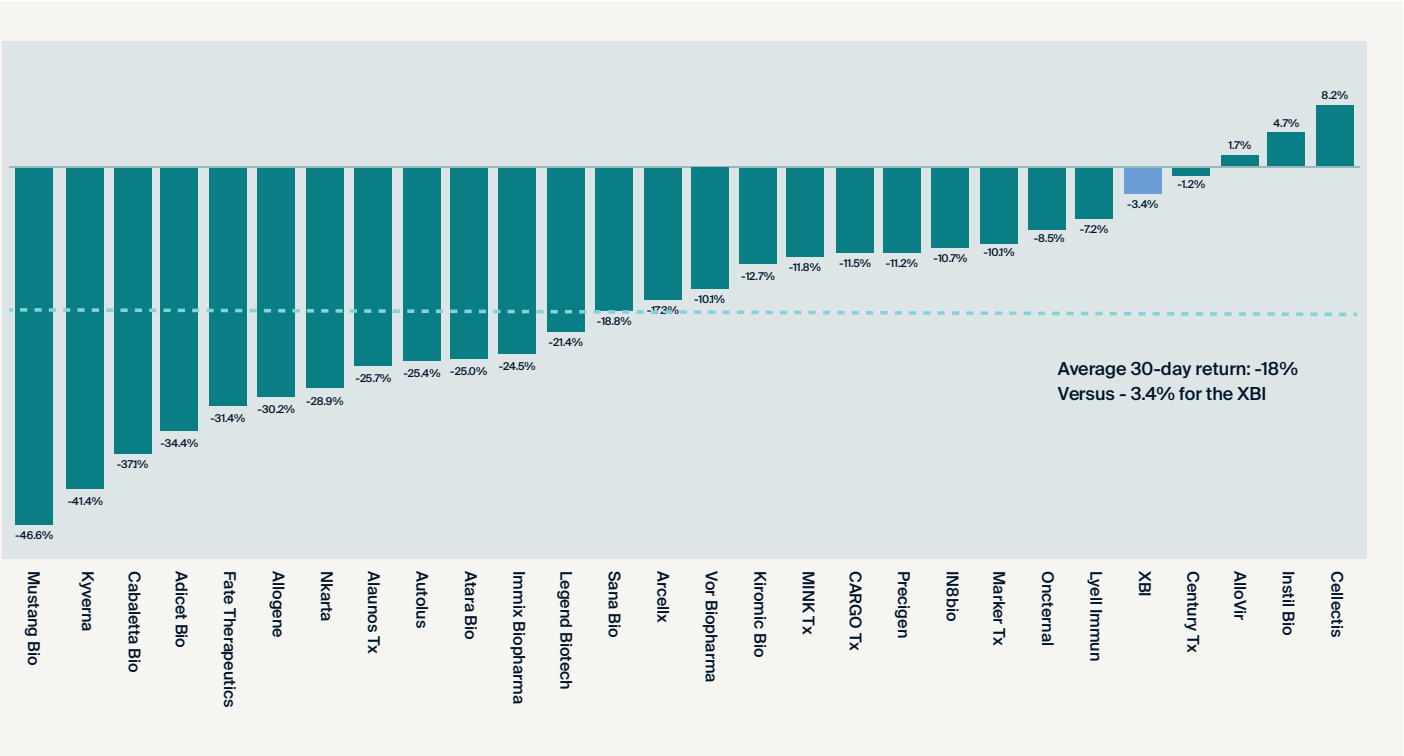
Looking deeper at investor pressures/ preferences

Investors, who often dominate biotech boards, generally prefer rapid exits based on Proof of Concept (PoC) data over long-term company building. This longstanding preference to exit pre-commercially if possible can conflict with building a sustainable commercial business driven by thoughtful corporate development strategy. Commercial de-risking requires attention and resources prior to PoC, but most investors consider this spend too risky. However, as indicated by consistent erosion of enterprise value experienced by unprepared first time *commercializers* – under spending on this critical activity is actually the greater risk.

Example: Cell therapies have advanced clinical de-risking but produce negative market returns resulting from failure to de-risk commercially *[figure 5]*

> *Biotechs face a simultaneous need to commercially de-risk assets for partnering AND plan for self-commercializing.*
>
> ***Ed Saltzman***

Figure 5
Share price return of US and European Public CAR-T and NK Cell Therapy Companies in Autoimmune and Oncology, Apr 11 to May 10, 2024



Source: Biopharmaceutical Sector Weekly Update – May 13, 2024: Stifel Healthcare

Planning for self-commercialization: How to build and implement a commercial culture

To better **prepare** for commercialization, we recommend that biotechs focus on the following critical strategies:

01 Bring onboard the right senior leadership and commercial expertise	Bringing in senior leaders with commercial experience will help shift the company's focus from purely clinical development to commercialization. These leaders can	provide the strategic vision, prioritization and operational expertise needed to navigate the complexities of bringing a product to market.
02 Start planning for commercialization much earlier	Successful biotechs understand they must shift their development strategy to focus on and align both clinical and commercial milestones. Early commercial planning is critical. By integrating commercial considerations into the development	process early on, biotechs will ensure that they are prepared for a range of commercialization challenges. This planning should include market analysis, competitive positioning, pricing strategy, and go-to-market plans.

When **implementing** commercial readiness we recommend the following:

01 Create a launch governance structure	This must be suitable for a start-up - empowering team members to act decisively in their roles but escalate major decisions and risks when necessary. Build confidence in launch teams by ensuring decisions are not reversed mid-process.	Implement a risk management plan to identify and address key issues, and secure support from senior leadership and the executive team for resolutions and mitigation plans.
02 Perform an organizational capability assessment during team onboarding	This will accurately identify current and future gaps in talent and infrastructure. Ensure appropriate investment to address these gaps and establish	multi-year resource plans based on current launch scenarios. Prioritize training needs correctly.
03 Develop a robust communication plan to ensure key stakeholders are informed of major decisions promptly and appropriately	Ensure all communications are results-oriented and efficiently disseminated to relevant internal team members and vendor partners.	Customize communication for each governance level based on the sensitivity and impact of the information on the organization.
04 Leverage external expertise	Emerging biotech companies can significantly enhance their commercial success by leveraging external expertise during the demanding commercial readiness phase. Many companies keep a small core staff and partner with experts for specific needs, with virtual commercial teams becoming more popular due to frequent and smaller launches.	Hire external partners with multiple launch experiences to validate brand strategy and plans, ensuring no critical elements are missed. Delegate project management responsibilities to experts, allowing core team members to concentrate on strategy development and tactic execution.

Summary

The commercialization of biotech assets presents a broad set of challenges and misconceptions. An imbalance of post-PoC biotech asset sellers and available large pharma buyers means the odds of securing a pharma deal at Phase 3 are significantly lower than those of obtaining regulatory approval for a clinically de-risked asset. Many high-quality assets will remain unpartnered, forcing the asset owners to “go commercial or go home”. Unfortunately, due to a misplaced priority on achieving a partnering deal or exit, biotechs often lack the necessary preparedness for commercialization, leading to a loss of shareholder value when commercialization becomes the most realistic option for wresting value out of development spend.

To navigate these challenges, biotechs must rethink their approach to commercialization. By building a commercial culture, incorporating commercial expertise into leadership, and focusing on early commercial planning, biotechs can better prepare for the transition from clinical development to commercialization. These strategic changes can enhance their commercial readiness and increase their chances of successfully bringing their products to market, ultimately driving value for shareholders and advancing the field of biotechnology.

Contact us to find out more about how our expert consultants can help you re-think and prepare to successfully commercialize.

Lumanity applies incisive thinking and decisive action to cut through complex situations and deliver transformative outcomes to accelerate and optimize access to medical advances. With deep experience in medical, commercial, and regulatory affairs, Lumanity transforms data and information into real-world insights and evidence that powers successful commercialization and empowers patients, providers, payers, and regulators to take timely and decisive action.

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