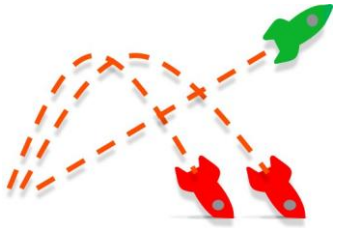

Lighting the Candle or Handing Over the Reigns?

Biotech's Tough Decision to Launch or Partner

by Markus Hauser, Christian Neckermann, Stefan Zillikens

Despite a growing trend of biotechs launching their first drug without a commercial partner, an analysis of all those companies pursuing this approach over the last decade suggests a 50/50 success rate as defined as an increase in share price - turning first launches effectively into a coin toss. Interviews with biotech CEOs offer a deep dive into the strategic, cultural, and operational pitfalls that trip up aspiring biotechs, from inherently flawed commercialization strategies to failing to achieve market readiness. Therapeutic focus matters: Rare disease and oncology companies fare well, while biotech companies concentrating on cardiovascular and infectious disease typically struggle. Ultimately, success demands more than a promising product - it requires intentional leadership, cultural transformation, and agility.

Launching a drug product is often seen as the final ascent in a biotech company's journey. Yet, for many firms, it's where the real challenge begins. Research on 2,000 Phase I compounds shows that less than 15% ever gain FDA approval (Schuhmacher et al., 2025) and of those, two out of three fail to generate sufficient sales to ever pay back the original investment (Hauser et al., 2017/2024; Ahlawat et al, 2017).

Despite these grim odds, an increasing percentage of biotech companies are choosing to "go-it-alone," especially in the United States - eschewing partnerships in favor of full commercial control. The appeal is undeniable: Own the upside, shape the narrative, and chart a future as a fully integrated biotech/ pharmaceutical company.

Abundant capital (at least until recently), availability of experienced talent, and capable vendors to outsource critical commercial functions make a go-it-alone increasingly doable (Harputlugil, 2021). But... is it a *good* choice?

To answer this question, we analyzed all 1,018 FDA approvals from 2015 to 2024, focusing on companies launching their first product independently without the help of a partner in the USA. Excluding private firms and those not listed on a US stock exchange, our sample homed in on those 134 companies that fit the criteria.

A Sobering Reality: The Coin Toss of First Launches

After gaining FDA approval, over half of the companies committed to launching independently suffer negative stock returns. For the 93 companies with continuing independent operations, the results are split evenly between positive and negative returns.

Of the 41 companies that ceased independent operations, the number of losses/bankruptcies were equivalent to that of successful acquisitions. In short, succeeding in commercializing a first product without the help of a mature bio/pharma appears to be, quite literally, a coin toss (Fig. 1: Launch Success).

A closer examination reveals that companies typically fall into one of three clusters (Fig. 2: Coin Toss Unveiled):

- Outright failures (bankruptcy, take-over at fire sale prices)
- Marginal performers (returns within ±25%)
- Outsized winners (companies achieving significant exits or stock performance with at least a doubling of the share price)

This tri-modal outcome distribution underscores the inherent gamble of launching alone.

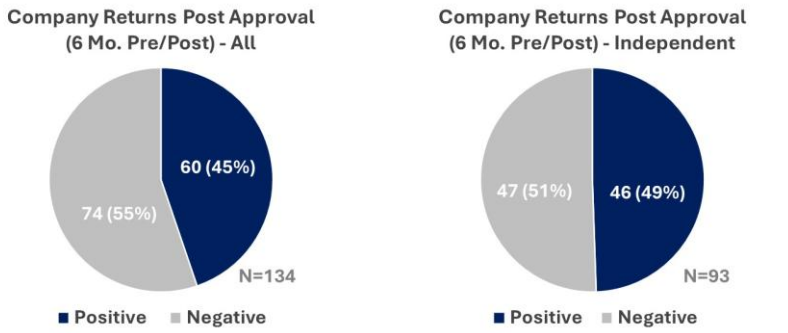

Fig. 1: Launch Success

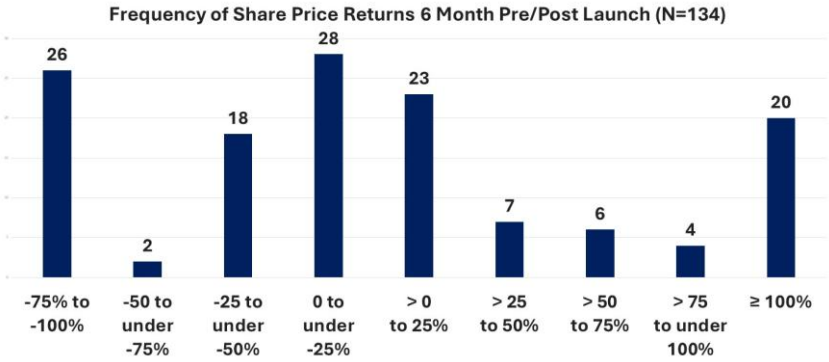

Fig. 2: Coin Toss Unveiled

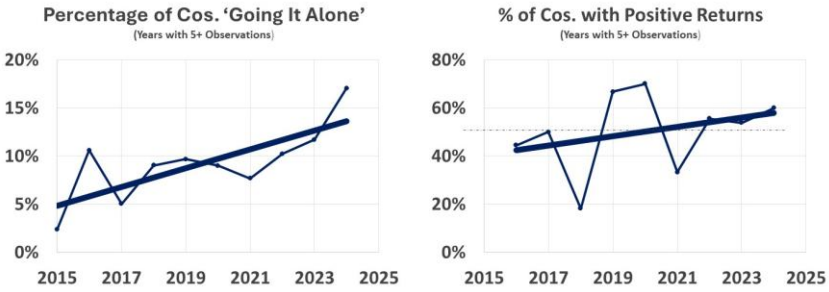

Fig. 3: Go-It-Alone Decisions vs. Success Over Time

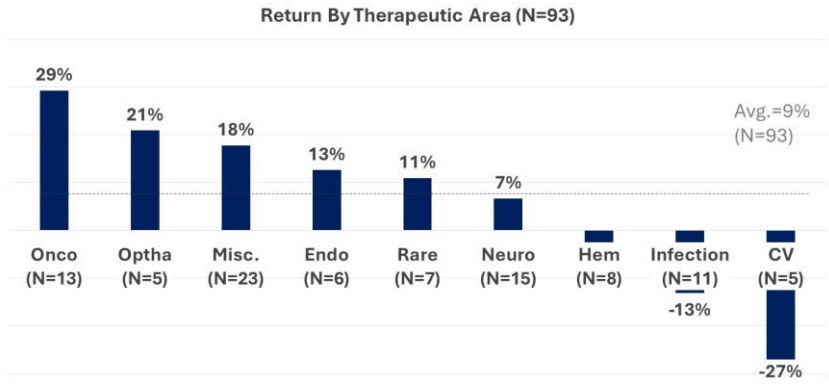

Fig. 4: Returns by Therapeutic Area

Trends and Therapeutic Nuances

While the number and percentage of companies opting to go-it-alone has increased over the years, their chances for success – defined as an increase in share price - continues to hover around 50% (Fig. 3: Go-It-Alone Decisions vs. Success Over Time). Having said that, it is worth noting that therapeutic areas appear to matter greatly for success. For example, companies launching products in

the rare disease space realize average share price returns 28% above those with more traditional therapeutic segments. In terms of therapeutic areas, strong positive returns are more common in Oncology (+29%), Ophthalmology (+21%), Endocrinology (+13%), Rare Diseases (+11%), and Neurology (+7%). In contrast, products in Cardiovascular (-27%), Infectious Diseases (-13%), and Hematology (-5%) historically perform poorly (Fig. 4: Returns by Therapeutic Area).

It is also worth noting that retail products were often acquired before reaching approval, suggesting that biotech companies realize the even larger challenges launching into mass markets and their stronger reliance on partnering or exits.

Typical Root Causes For Failures

Reasons for failure vary, but typically fall into a few categories:

- **Science Hubris:** Science is the foundation of any successful biotech. The love for science, however, can lead founders and boards with limited commercial experience to believe that the product sells itself. It never does! The lack of investment/commercial preparedness associated with this belief is a frequent cause for disappointing launch performance.
- **Shortcomings of Clinical Trials:** Failure to define a) the right clinical end-points for b) the right patient populations at c) the right time for optimal development is probably the most damning misstep of biotechs aspiring to write their own ticket. The imbalance between what the product can credibly deliver with what is valued by stakeholders (patients, HCPs, payers, regulators) often leads to a market mismatch that is difficult, if not impossible, to correct later.

  Several drugs developed for heart failure are recent examples for products where the clinical trials included too broad a patient population. Including less severe or unsuitable patients dilutes the capacity of any trial to demonstrate clinically meaningful efficacy (comparing the primary end-point of e.g. patients with NYHA Class III/IV to the results for the entire patient cohort). Failure to get it right generates data that does not support rapid, widespread use and – for example – in the case of Verquvo, results in US sales of $21M for the first half of 2025 – 4.5 years after launch.
- **Devolving Company Culture:** As companies mature from pre-commercial to a commercial entity, the necessary rapid growth and shift in mind-set often comes at a cost. The basis of trust – so central to a company's identity/ employee engagement - often shifts from a personal 'I-know-you-will-do-what-you-said-you-would' to only trusting systems and processes. With this re-orientation, long-time employees might feel questioned in their integrity, micro-managed, or overburdened with what they consider unnecessary bureaucracy. What is valued shifts from getting work done to following the process (and getting work done). With rapid expansion also comes the risk of lowering hiring standards or diluting a strong company culture.
- **Misguided Commercialization Strategy:** The road to commercial fiascos is paved with failures of commercial strategy. From under-investing, over-extending (often launching globally too early), murky positioning and messaging, to over/underpricing a compound – the list of potential pitfalls is long.

  A recent example is Lexicon Pharmaceutical's Inpefa, an SGLT1/2 inhibitor that was developed to combat heart failure and was priced at less than half of other heart failure drugs. Consequently, the company could not compete in the market access 'game' of established players. Another interesting example are bio-

similars where companies often fail to account for economic realities and the incentive system of relevant actors. Extavia, one of the first biologic 'generic' (it was really a bio-identical to Betaseron), hovered around less than 1% market share for years (San-Juan-Rodrigues et al., 2019) because Sandoz/Novartis launched the product at a low price point. They failed to realize that rebates are more important than the absolute price and that even a small rebate on the original product, Betaseron, was more attractive to PBMs than even a 'no-cost Extavia'.

- **Lack of Resources:** Under- and delayed investment in commercial, manufacturing, or supply chain resources have been frequent causes for commercial failure. Whether it is Bayer's inability to supply sufficient Betaseron to meet early demand, or the quality problems related to Genzyme's Cerezyme/ Fabryzyme (Bethencourt et al., 2009) – the unwillingness to invest in redundancies/ sufficient capacity left the door open for competitors to enter markets that these trail blazers created. Similarly, drug launches fail when first-time commercializing biotechs compete against large pharma and under-invest in commercial resources, whether it is the size of the sales force or the marketing budget. No matter what, share of voice (personal and non-personal) matters when it comes to driving share of mind and market.

- **Flawed Execution:** Many disappointing launches can be traced back to failures to adapt with agility to an evolving local market and to the implementtation of a 'one size fits all' sales and marketing approach. Companies who recruit from large pharmas frequently fall into this trap. The complexities of a large pharma company often require a simple 'everyone follows the same playbook' approach. For instance, every rep will have the same arsenal of sales tool, the same budgets, the same targeting priorities. At best this is inefficient and at worst, it hurts the long-term prospect of the product. Take sampling for instance: carpet bombing the nation with free samples often backfires. Instead of driving a successful trial, customers with a great product experience feel led on when they try to fill a commercial prescription that ends up not being reimbursed by their health insurance. The ensuing disappointment can undermine the willingness by HCPs and patients to ever give the product a second look.

Executive Takeaways: Strategic Reflections

1. **FDA Approval Is Not the Finish Line**: Approval is a critical milestone, but does not guarantee market traction, reimbursement success, or investor reward. Robust clinical/commercial development and post-approval strategies are essential to sustaining performance.

2. **Risk-Return Imbalance**: The combination of high capital burn, operational challenges, and market uncertainties makes independent commercialization financially very risky. Although high rewards are possible, the odds are essentially 50/50 - a real coin toss. The tri-modal distribution of outcomes should give executives pause. A few companies achieve outsized wins, while many fall flat or fail, reinforcing the need for a clear risk-management strategy.

3. **Chosen Therapeutic Area Affects Outcomes:** If a product targets cardiovascular or infectious diseases, the data suggests a red flag against a go-it-alone strategy. Conversely, rare diseases and certain niche therapeutics may offer a higher likelihood of success.

4. **Strategic Alternatives – Early and Continued Considerations:** Exploring partnerships, co-commercialization, or early acquisition discussions can help mitigate risks.

Flexibility and openness to strategic alternatives are crucial components of good governance especially for companies developing retail, cardiovascular, or infectious disease products.

5. **Need for Commercial Expertise Early**: Firms must shore up talent in marketing, sales, and market access earlier. These functions are often underdeveloped in pre-commercial biotechs. To manage budget constraints, companies may need to engage fractional biotech teams, necessitating leadership to rethink standard staffing models. Boards must be diversified early to include commercial experience and be equipped to challenge pervasive scientific optimism with market realism.

6. **Selective Expansion of the Organization**: The risk of hiring too fast or onboarding toxic individuals during rapid growth is high. Companies must develop robust screening and onboarding processes that prioritize cultural fit over speed.

7. **Integration of a Commercial Culture**: Leadership must facilitate the cultural shift from an R&D-centric environment to one that incorporates commercial priorities. Leadership must educate on commercialization, market dynamics, and operational excellence to create a company-wide understanding and appreciation for commercial complexities and contributors to a successful launch. With a growing need for systems and formalized processes, leadership must support the organization in maintaining employee trust, helping staff navigate changes in autonomy, roles, and expectations.

8. **Fit-for-Purpose Structures**: Leadership should design adaptive organizational structures that support rapid decision-making, localized execution, and scalability. Cross-functional collaboration becomes essential and requires coaching in matrix leadership and effective conflict resolution.

9. **Balance of Ambition and Discipline**: Leaders must pursue bold goals while rigorously validating market assumptions and customer needs. Executives must be open to partnership or acquisition discussions - not out of weakness, but as a means to enhance value creation. Strategic choices - whether to launch, partner, or exit - should be framed by what best serves patients, employees, and investors. Potential biases need to be put in check. Leadership must develop and stress test go-to-market strategies, including contingency plans for failure or underperformance.

10. **Execution Excellence:** Agility achieved by leaders who build teams and infrastructure that support execution tailored for geography, segment, and evolving stakeholder needs – avoiding "one-size-fits-all" commercial models.

Closing Thought: Be Bold – Be Smart

Biotech is a sector where ambition meets uncertainty. It is not a sign of weakness to choose partnering or acquisition in the pursuit of maximizing corporate value. It might very well be the right choice for investors, patients, and employees. For those companies determined to go-it-alone, it must be clear that launching a drug requires more than just a strong product. It necessitates intentional leadership, a scalable human resource strategy, and organizational agility. Success hinges as much on how executives build and lead the organization as it does on the product itself. Companies must invest early in commercial talent, culture transformation, and strategic governance, or risk falling victim to biotech's 50/50 launch ‘gamble’.

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