5 ways for emerging biotechs to launch smarter

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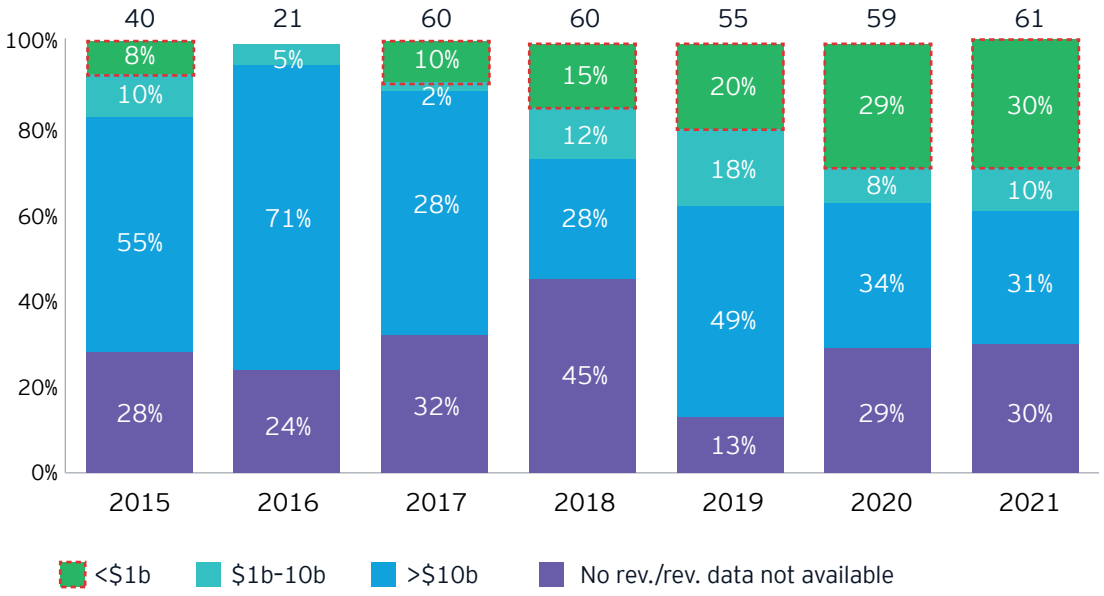
Introduction

Amid evolving market conditions, small and midsize biotechnology (biotech) companies have been increasingly active in developing novel drugs and securing drug approvals from the Food and Drug Administration (FDA). Today, smaller companies (those with less than $1b in total sales) represent a significant share of new molecular entity (NME) market approvals and launches, growing from 10% in 2017 to 30% in 2021.[1] As a result, small and midsize biotech valuations have been rising, thereby making them less attractive for acquisition by larger players and forcing these biotech companies to launch on their own.

Launching a new drug can be challenging and complex, and more than two-thirds of biopharma products launched since January 2020 have failed to meet analyst expectations.[2] However, overall launch success has been disproportionately lower for biotechs in the last two years in the US, with 59% of those misses from companies with less than $1b in revenue.[3]

Only a small percentage of emerging biopharma companies exceeded sales expectations,[4] further emphasizing how challenging commercial execution can be for small and midsize biotechs pursuing their first or second launch.

% share of NME approvals by revenue class of company, 2015–21



[1] GlobalData; EY analysis.
[2] EY analysis.
[3] Ibid.
[4] Ibid.

Current conditions

Traditionally, biotech M&A activity has occurred prior to product commercialization, often in Phase 2 or 3 of clinical development. However, in the first half of 2021, valuations for early-stage small and midsize biotechs reached historic levels due to increased interest in new technologies and therapeutic development amid a significant innovation deficit among large biopharmaceutical companies. According to the 2022 EY M&A Firepower report, acquirers paid, on average, a 62% premium for public companies relative to their share price one month earlier. At the same time, funding alternatives such as IPOs and special purpose acquisition companies (SPACs) reached a fever pitch across the industry. This provided these target biotech companies little financial pressure to sell and a stronger negotiating platform to demand higher deal premiums, especially if their drug belonged to a new therapeutic class expected to be important for future growth.

For these reasons, today's biopharma acquirers are taking a more cautious approach and increasing their value expectations for drugs, devices and diagnostics. Although larger biopharma companies are aggressive in their pursuit of external innovation to stay competitive, today's acquirers prefer to engage in collaborative and strategic partnerships as they wait for biotechs and their products to mature, demonstrate potential value, and become de-risked. Additionally, the need for external innovation to achieve future growth targets, combined with the high price tags for M&A, further emphasizes the need for biotech to demonstrate value through launch success and accelerate partnering. Partnership and alliances remained strong in 2021, and it is notable that the average upfront payment for biotech deals dropped from $84m in 2020 to $53m in 2021, signifying a shift toward smaller investments focused on hedging development risk.[5] In addition, bolt-on deals comprised 88% of deal volume in 2021 – demonstrating an appetite for less risky deals among larger biopharma companies.[6]

Given these changing dynamics, small and midsize biotech companies must substantiate the value of lead and follow-on development programs to improve asset attractiveness for investment and acquisition through both a successful launch and recurring revenue of their products. Despite the urgent need for homegrown commercialization among biotechs, the launch process is often a new endeavor for these enterprises since they have been built and structured primarily to research and develop novel therapeutics. As a result, many emerging biotechs lack the infrastructure and capital necessary to build and execute successful launches. In addition, market access challenges and formidable competition, as well as other internal challenges, such as suboptimal skill-set alignment, often prevent these companies from effectively developing and executing launches on their own.

The path forward for small and midsize biotechs

Considering the conditions described above, we recommend that small and midsize biotech focus on the following five key pillars to prepare for and enable a successful launch.

[5] Ibid.
[6] Ibid.

1 Design an operating model that drives executional effectiveness.

From market access to sales, supply chain, and regulatory, a cross-functional mindset is essential for a successful biotech launch.

This involves building out a launch team with diverse skill sets and capabilities early on, particularly for biotechs launching a product for the first time with limited resources. Collaboration, accountability, and diversity of thinking inform a wide variety of critical launch-related activities, including pricing, marketing spend, and salesforce deployment. Without proper planning and prioritization around key activities and resources, the launch team likely will find it difficult to execute an effective launch due to significant challenges in catching up on related tasks that require long lead times. It is critical for organizations to develop execution plans, include associated investment that enables the launch team to build a deep understanding of the market and strategically position the company's products for success.

2 Execute an effective and fit-for-purpose go-to-market plan.

Commercialization budgets are typically large, and their upfront spend is not at risk, assuming regulatory approval.

Biotech companies have to utilize a fit-for-purpose, prioritized, and smaller budget, and yet they need to be able to execute competitively in the marketplace. Emerging biotechs should take advantage of the increasing role of medical affairs, advocacy, and potential provider partnerships in their go-to-market strategy. Innovative and effective plans to activate key opinion leaders prior to launch are fundamental to support a robust product introduction. Relationships with advocates and influencers are essential in bolstering the clinical need and health-economic value of a new product relative to the standard of care or other interventions in the market. In addition to conveying a compelling value story, emerging companies should engage payers early to understand the drivers and potential barriers for product uptake, including nontraditional payers such as retail stakeholders. Moreover, the COVID-19 pandemic has accelerated the shift beyond traditional face-to-face interactions to more digitally enabled communications. As such, biotech companies need to plan, build and implement both an omnichannel engagement model to interact with customers and an end-to-end positive patient experience. It's also important for these companies to understand which targeted stakeholders to engage, when to engage them, and which channel is most appropriate. This mindset is essential to drive a product's success and penetration in the market upon launch.

3 Be strategic about market access and pricing.

Another key pillar for a successful launch, this approach involves carefully developing estimates for potential product value by applying risk scoring to assess pricing and guide strategic choices, building robust forecasting models, and establishing a methodology to evaluate the probability of technical, regulatory, and market access success for each product.

It's critical for the launch team to develop an early understanding of how diverse stakeholder groups will perceive a product. This will enable the team to anticipate and plan for any potential obstacles or challenges that may arise during launch. The impact of not doing so can be significant, including underperformance and missed first-year forecasts. Small and midsize biotechs also need to understand the payer perspective on unmet need, comparators, and coverage and reimbursement processes early in the planning process so that the company can plan for and generate the appropriate evidence ahead of launch. The launch team also needs to assess the budget impact in the context of the treatment paradigm and outcomes when they establish the list price, net price and coverage goal for the product. And because many of these tasks must be completed virtually, many companies also need to evaluate which payers to engage and how to engage them — including the pre-launch exchange of information — to articulate the value proposition of the product and potential negotiations at launch.

4 Prioritize data foundation, analytics, and monitoring.

Strategically collecting, analyzing, and monitoring data is essential in establishing a solid foundation to deploy a smarter, more efficient go-to-market strategy with limited resources.

Small and midsize biotech companies should leverage their internal data and external datasets to uncover market insights as well as physician and patient preferences and behaviors. Additionally, biotech companies are now applying machine learning and predictive analytics to a wide range of commercial use cases, including the identification of drivers for uptake and predictions on how providers, patients and payers are likely to react to the entry of a new product. Using predictive analytics also can help launch teams anticipate pricing and reimbursement hurdles and understand how to improve patient access.

Advanced and predictive analytics can provide sales and marketing functions with real-time insights into content and channel preference based on the historical behavior of physicians and patients, increasing the likelihood that the right message will get to the right stakeholder through the optimal method. To maximize the effectiveness of the field force, organizations rely on clean and accurate customer data and performance metrics to properly align territories and incentivize sales representatives. All of these capabilities need to be baked into the strategic planning of any launch from the very beginning. Delayed decision-making around data and analytics considerations is a common industry pitfall that ultimately creates significant challenges in the later stages of product launch.

Implementing the foundation for a robust analytics and omnichannel model early will improve the quality of the insights extracted from data, increase overall organizational agility and establish effective closed-loop feedback mechanisms, resulting in a quick adaption of messaging to customer preferences and seamless redeployment of resources. In addition, monitoring performance using consistent metrics across the product portfolio will help teams navigate a rapidly evolving landscape by identifying potential issues and enabling the team to course-correct early in the launch process.

5 Conduct market-shaping activities early.

Leveraging a multi-stakeholder approach to support market-shaping activities and increase awareness and adoption of new therapeutics begins long before launch.

Collaborating with influential health and patient advocacy organizations, community leaders, and market influencers is especially important for new therapeutic indications, as shaping an unmet need with novel products in novel landscapes can take considerably longer than it does in previously established markets. To be successful at launch, it is essential that biotechs understand the nuances of the landscape, evaluate the market, and effectively communicate value and unmet needs throughout launch engagements.

Most successful companies begin these activities during the clinical development phase to transform disease perception and adjust the product profile before launch. The launch team will need to begin by forming strong partnerships and engaging early with patients, caregivers, and advocacy groups to understand their journey and the obstacles they may face in accessing treatment and help to address value gaps. Patient advocacy groups are tremendously influential in accelerating funding and access for innovative treatments by conveying their patients' pressing needs to regulators, policymakers, and budget holders to drive maximum impact.

In addition, building valuable relationships, deploying disease-state education programs, and priming the market can help stakeholders analyze data to source a stronger, more nuanced understanding of the market and unmet patient needs. If market-shaping activities are executed effectively, biotechs will be able to transform existing market structures to improve therapy awareness and maximize patient access and uptake upon launch.

Summary

A successful launch can establish value and change the narrative in negotiations for small and midsize biotechs. With over $1t in collective firepower (i.e., capacity to fund transactions) in 2022 — amid looming loss-of-exclusivity concerns around patent expiration — biopharma is poised to invest in innovative products to fuel growth. Strategic partnerships offer significant value to biopharmas and allow small biotechs to focus on their core skills, including discovery, research, and development. However, biotech companies may not be able to rely only on M&A and will have to quickly learn how to effectively and competitively launch products before realizing an exit strategy.

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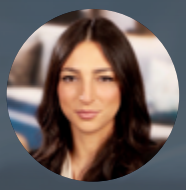

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