Optimizing Commercial Success for Emerging Biopharmas

Key strategies to measure success

Situation

Achieving commercial success for a new drug has always been challenging, but the past 10 years have proven to be even more daunting, but there are still successes to analyze.

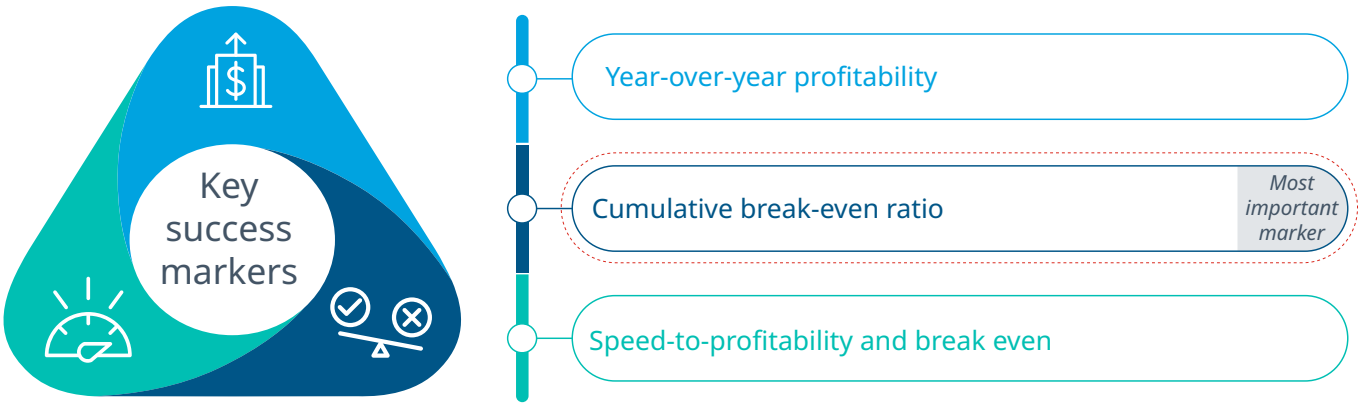
Our analysis of over 1,500 launches from 2010-2021 uncovered some interesting launch metrics. Only one in four new-to-brand patients who attempted to fill a launch brand was successful due to payer controls. Additionally, more than half of brands miss their first-year forecast, and among those, only 20% get back on track. In that first year, as many as 70% of patients on newly launched brands are supported by patient assistance/bridge programs, at very high cost to the manufacturer.

Challenge: Key success measurement traits

While launches remain challenging, IQVIA's analysis of 505(b)(2) pathway drugs, which offer some cost relief by lowering upfront development costs, revealed key insights that could help emerging biopharma (EBP) companies.

In looking at a subset of EBPs, IQVIA identified a number of key measurement traits that could be used to help EBPs measure the success of their commercial investments dollars:

- Year-over-year profitability, or net revenue surpassing commercial costs.
- Cumulative break-even ratio, or a positive return on investment (ROI) on the total dollars invested commercially over the full life of the product, starting three years pre-launch.
- Speed to profitability, or the time a product takes to break even and start returning profits. Products that achieve ROI have high speed to breakeven and profitability and a high cumulative break-even ratio.



Customer success case study

One EBP company that received FDA approval launched into the very competitive ADHD market. At the time of launch, there were more than 25 products already in the market, including several generics.

While this company had the benefit of reductions in upfront investment costs due to the 505(b)(2) classification for their product, this alone was not enough to make them immune to broader cost pressure trends. They needed a sound clinical plan paired with an equally strong commercial strategy.

Their product was differentiated and addressed several unmet needs for patients that contributed to launch success:

- **Lower propensity for abuse**, thanks to one of its chemical entities that got a favorable abuse profile from the DEA.
- **Rapid onset and sustained duration of effect**, which helped patients who wanted better efficacy in the morning, or a smoother benefit as the drug wanes during the day.

Another critical success factor for this company was share of voice. The company needed prescribers to understand, remember, and act upon the information they had about the product. The sales force needed to be there to explain the benefits and establish a foundational understanding among prescribers. The omnichannel efforts drove frequency and recall in the customer mind space, and medical advocacy was critical in establishing credibility as a late entry product in a very established market. The company found that prescribers appreciated their product's differentiators increasingly over time, so they continued to lean into them from a marketing perspective.

However, the biggest hurdle to overcome was how to succeed in such a competitive market with many access challenges; to address this, copay support was foundational for the launch and starting product uptake. The company also focused their commercial

efforts where formulary coverage was established and favorable, and scaled investments to align with the regional payer environment.

Companies only get to launch once, but in 2024, they have a little more time — and thus more time to adjust to the market, moving their resources where they think they will have an impact and where payer coverage is increasing. The company took a regional approach, focusing on launching their salesforce in one region where the payer environment was more favorable. Then, over time, expanded from there, increasing their presence in other regions as they accumulated formulary wins.

With more time for launch success, EBPs want to have all their resources readily available to make an impact as soon as the environment allows for that. This company put differential review processes around resource allocation and payer wins.

If EBPs get patient access right and allocate their resources where they're going to make a difference, and layer that with good product differentiation, they're in a good position to do well in the marketplace.

Five key factors for EBP launch success

1 Develop a winning strategy

As with a branded product, 505(b)(2) and other EBP drugs require early and highly effective launch readiness preparation across all aspects of launch. Companies must have a great understanding of their forecast and market opportunity: the managed care challenges and payer resistance they might face, and the go-to-market model they need to build to achieve that forecast.

2 Minimize access challenges by creating value story

Negotiating payer restrictions, access, and price requires a strong value story to reach the patient population. Once companies understand where their product fits into the market, they can develop the evidence they need to tell that value story and drive uptake over the first 12-18 months.

3 Drive medical education and brand awareness

Education of thought leaders and treating physicians requires a solid scientific story that builds credibility, especially in highly competitive markets. Once companies have developed that story, it's critically important to disseminate it the right way.

4 Construct a scalable data and tech infrastructure

Increasing speed to action requires a comprehensive data strategy supported by scalable technical infrastructure, so companies know when the time is right to unleash their resources and how to continue to optimize their actions.

5 Deploy an optimized go-to-market model powered by artificial intelligence and machine learning (AI/ML)

The go-to-market model is not going to be static. Focused patient and healthcare provider targeting, informed through AI/ML, enables dynamic resources based on their preferences.

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Connected Intelligence brings together IQVIA's unique portfolio of capabilities to create intelligent connections across its unparalleled healthcare data, advanced analytics, innovative technologies, and healthcare expertise to speed the development and commercialization of innovative medicines that improve patients' lives.

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