EXECUTIVE INSIGHTS

Shareholder Value Creation for First-time Launchers: Two Decades of Learnings

An increasing number of biopharma companies are transitioning from development to commercial stage by launching a first product. This is a critical time in a company's journey, one fraught with high investor expectations, which involves making difficult decisions to ensure successful transformation into a commercial organization and creation of shareholder value.

After spending years investing substantial capital to develop a first product, first-time launchers need to deliver on commercialization and revenue generation. The bar for commercial success is now higher than ever before. Not only must first-time launchers quickly scale their commercial organization and build competencies across numerous functions, but they must also do so while facing growing market access constraints, increasingly complex customer ecosystems and rising investor expectations.

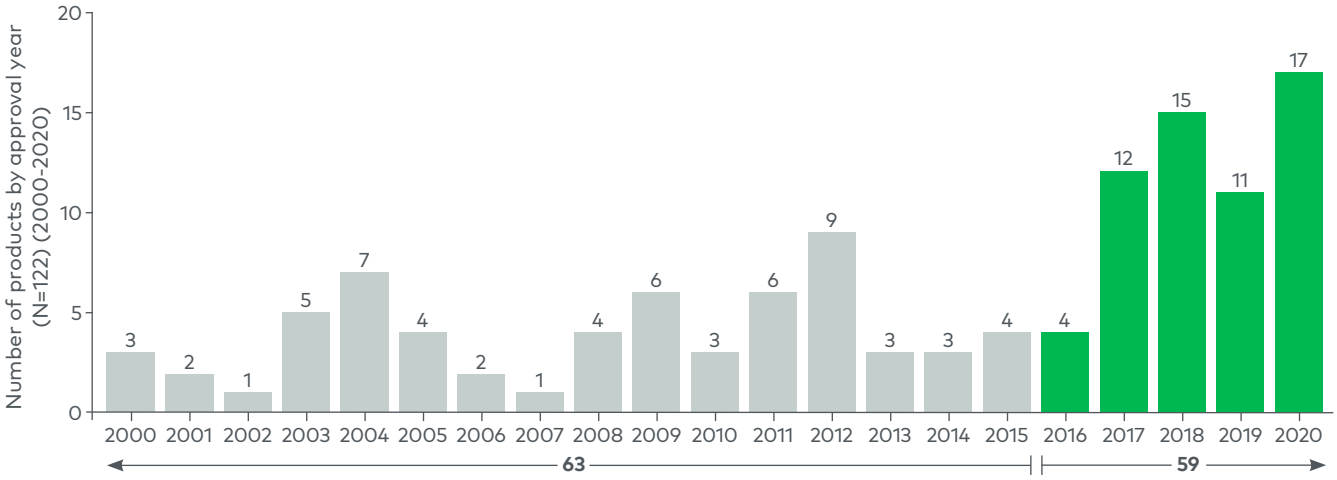
In this *Executive Insights*, L.E.K. Consulting looks back at two decades of first product launches to understand how these companies perform in the first two years after launch, and what factors drive launch success and value creation.

First-time launchers on the rise

L.E.K. identified 122 public companies that received a first Food and Drug Administration (FDA) approval of an innovative therapeutic substance between 2000 and 2020, and subsequently led or participated in that product commercialization in the U.S. (see the Methodology section for further details on product inclusion and exclusion criteria).

The number of first product launches has significantly increased over time — with 63 launches from 2000 to 2015 followed by another 59 between 2016 and 2020 (see Figure 1). Almost 60% of these launches targeted orphan or oncology markets.

Figure 1
Number of first-time launched products by public companies in the US per year

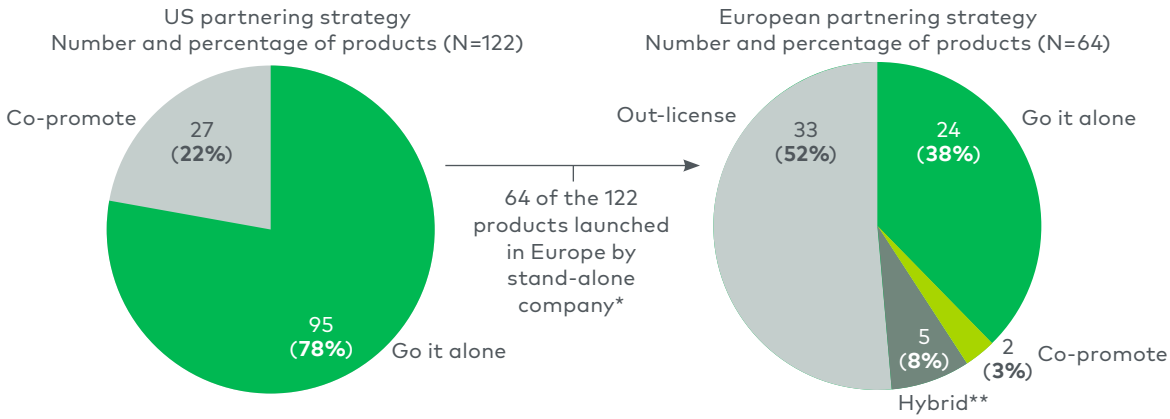


Note: Methodology section for inclusion criteria to define first product launches between 2000 and 2020
Source: L.E.K. analysis of FDA approvals, company financial statements, press releases, and other articles

Partnering trade-offs

One of the most critical decisions for first-time launchers is whether to go it alone or partner. In the U.S., the predominant commercialization model has been to go it alone, with 78% of companies opting for this strategy, while the rest co-promoted with a partner (see Figure 2).

Figure 2
First product launch partnering strategies for US and Europe



*Company no longer considered stand-alone at date of acquisition announcement; product considered launched if launched in at least one European country; data are as of summer 2022 and may not include products approved and launched after this date
**Includes companies that retained control of major European markets but out-licensed to a subset (e.g., in Eastern Europe)
Source: L.E.K. research and analysis of Pharmaprojects, Citeline, company financial statements, press releases and other articles

While going it alone enables biopharma companies to control their product commercialization and maximize value retention, this direct model is not without risks, as it requires building various capabilities and accessing significant capital within short time frames.

Europe presents different market dynamics and trade-offs. About half of first products commercialized in the U.S. from 2000 to 2020 were subsequently launched in Europe within two years. For those, out-licensing was the dominant commercial strategy (see Figure 2). We found 24 companies that self-commercialized their first product both in the U.S. and in Europe. The majority of those companies targeted orphan markets (including rare oncology diseases) with addressable European markets of at most tens of thousands of patients.

First-time launch performance

Nearly 20% of first-time launchers were acquired within the first 24 months following FDA approval, including 10 in the first year after launch and an additional 13 in the following year. To date, nearly 55% of first-time launchers from the past two decades have been acquired, which demonstrates just how hard it is for a first-time launcher to remain independent.

When participating in the commercialization of their product, first-time launchers often fail to drive early product adoption and deliver meaningful revenues. Actually, these companies achieved only modest product sales in the U.S., with a median of $32 million in the first 12 months of launch and $92 million in the first 24 months (see Figure 3). There is, however, a wide distribution of revenue performance, with 77% of first-time launchers not reaching $100 million within 12 months and 7% exceeding $300 million within this time frame.

Figure 3
U.S. product revenues 12-and 24-months post-approval

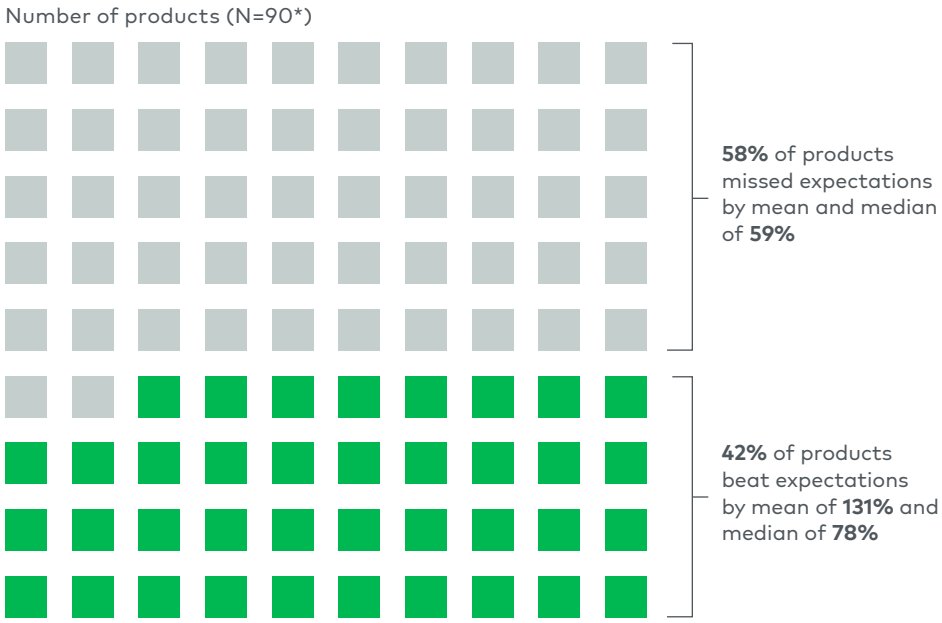
	12 months (N=106*)	24 months (N=91*)
Median (millions of USD)	**$32**	**$92**
Mean (millions of USD)	**$135**	**$312**
Distribution of cumulative revenue (percentage of products)		
• Less than $100 million	77%	51%
• $100 to $300 million	16%	30%
• Greater than $300 million	7%	19%

*Excludes products where acquisition of FPL company was announced, products where FPL went bankrupt or out-licensed the product in the US within the relevant timeframe and products where revenue data was not available; Evaluate Limited estimates for 2022 were used for some companies launched in 2020
Note: FPL=first product launch
Source: L.E.K. analysis of Evaluate Limited, company financial statements

Misaligned expectations

First launches can underperform for myriad reasons, but many are the result of consequential gaps between bullish investor expectations and cautious internal company projections. Comparing the actual U.S. product sales of first product launches to sell-side analyst forecasts prior to launch reveals some sobering results. Sixty percent of products underperformed analyst expectations 12 months after approval (see Figure 4). And among both underperforming and overperforming products, the discrepancies between pre-launch forecasts and actual results were often striking. Outperforming products beat forecasts by a median of more than 75% while underperformers missed forecasts by a median of 59%, with a quarter of underperformers missing forecasts by more than 85%.

Figure 4
US product sales 12 months post-approval relative to analysis expectations



*Excludes products where acquisition of FPL company was announced prior to 12 months after FDA approval, products where FPL went bankrupt or out-licensed the product in the US prior to 12 months after FDA approval, products not yet 12 months since US approval and products without available revenue or forecast data
Source: L.E.K. analysis of Evaluate Limited, company financial statements

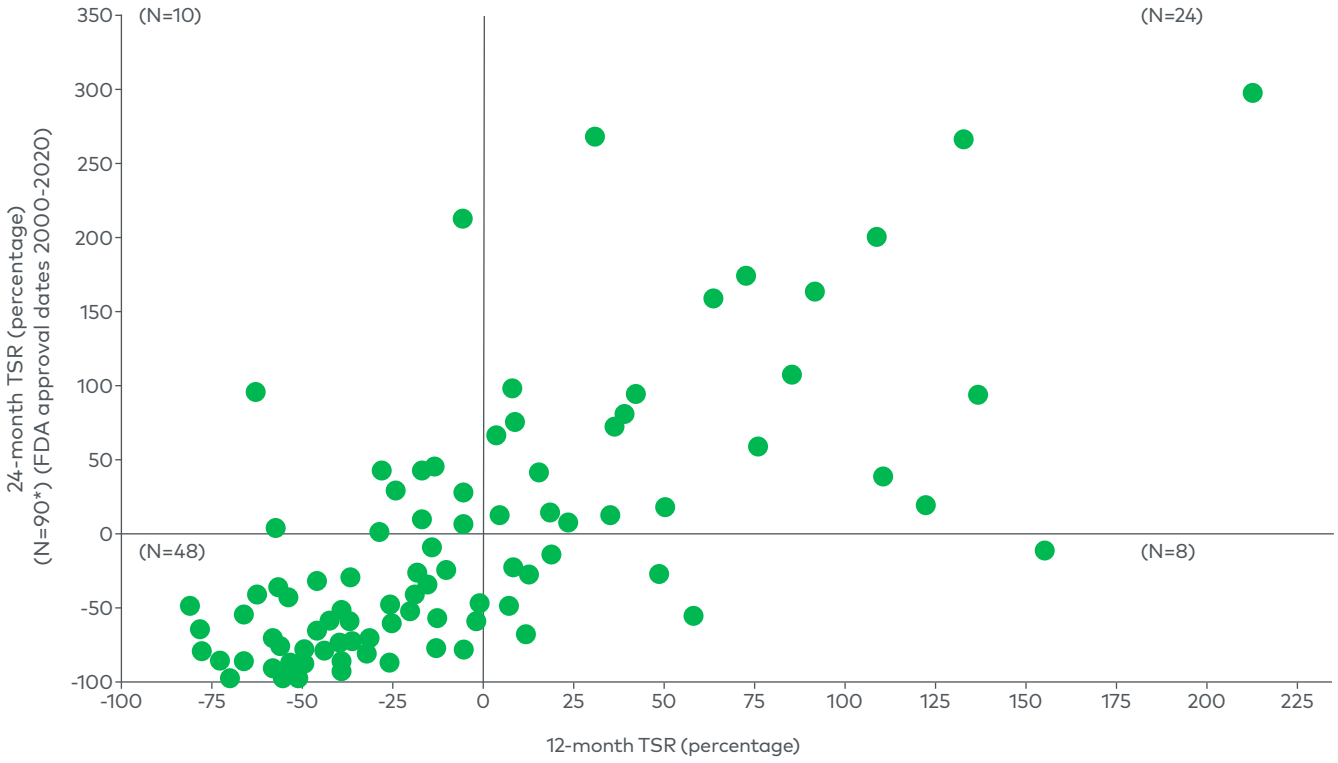
Shareholder value creation through first product launch

Overall, the 122 companies analyzed by L.E.K. have created more than $400 billion to date in shareholder value, split between $320 billion from 66 acquisitions happening after first product launch and $80 billion reflecting the current equity value of the 56 remaining stand-alone companies.[1]

Still, a sizable portion of these companies failed to create shareholder value around the time of first product launch. Of the 90 stand-alone companies that actively marketed their product two years after approval,[2] nearly two-thirds generated negative shareholder return, with 53% destroying value at both the 12- and 24-month mark (see Figure 5). Only 27% of companies were able to consistently create value in this two-year time period.

Revenue performance has a significant impact on a first-time launcher's cash flows and valuation. Given the wide disparity in revenue performance among first-time launchers, it should come as no surprise that many first-time launchers fail to create shareholder value within the first two years. We found that the magnitude of difference between forecast and actual sales is more closely correlated with shareholder return than is the absolute value of U.S. product sales; nearly three-quarters of the companies that underperformed Street expectations at two years destroyed shareholder value at two years.

Figure 5
FPL company total shareholder return at 12- and 24-months post-approval



*Excludes products where acquisition of FPL company was announced prior to 24 months after FDA approval, products where FPL went bankrupt or sold or out-licensed the product in US prior to 24 months after FDA approval and products not yet 24 months since FDA approval
Note: TSR=total shareholder return; FPL=first product launch; FDA=Food and Drug Administration
Source: L.E.K. analysis of S&P Global Market Intelligence

Conversely, more than 50% of the companies that outperformed Street revenue expectations at that time point created shareholder value. Notably, 10 companies failed to generate value during the year of launch but generated positive returns in the second year. These companies either experienced a slower-than-expected launch and then corrected their growth trajectory or had positive pipeline readouts that improved share price performance in the second year after launch.

Partnering in the U.S. is a decision that can impact shareholder value creation. Companies that opted for a co-promotion generated more shareholder value than those that went it alone; 45% of first-time launchers that co-promoted in the U.S. generated positive returns at the two-year mark compared with 35% of first-time launchers that entered the U.S. alone. While this may be the result of a selection bias on the part of pharmaceutical partners seeking co-promotion agreements on only the most promising drugs, we found that first-time launchers co-promoting in the U.S. uncovered significant value from their partner's existing capabilities and established relationship with providers and payers.

Key success factors for first-time launchers

Given the increasing contribution of development-stage companies to biopharma innovation, L.E.K. anticipates the number of companies participating in the commercialization of their first product to continue to increase in the near future. To be successful in this journey, first-time launchers will need to pay close attention to four success factors:

1. Design a clear-sighted operational scale-up

The launch process is complex, often involving unforeseen challenges around everything from supply chain coordination to patient support. Given the focus of first-time launchers on minimizing burn rate and reducing dilution, some of them delay the funding of market-shaping activities as long as possible, favoring just-in-time investments at key de-risking clinical and regulatory milestones. This guarded approach often puts key commercial activities at risk and leads to launch delays that compromise the overall revenue performance given the difficulty in recovering from a slow start and early missteps.

Instead, first-time launchers must invest early, typically two to three years before approval, in building commercial, medical and enabling infrastructure, even while significant technical and regulatory risk around their product remains. Hiring a commercial leader is a critical first step to jump-start activities such as designing the desired end state for the organization, building teams in critical functions and engaging with key stakeholders to gain early market insights. Although launch team members wear a lot of hats in these organizations, they

must be diligent about identifying interdependencies across launch activities and remain coordinated through cross-functional teams to orchestrate the launch journey.

Equally important is the process of setting mechanisms to collect internal and external market information in real time, enabling first-time launchers to pressure-test product positioning, monitor progress and correct the launch strategy when needed. To collect this information in today's environment, customer-facing teams need to take advantage of remote engagement solutions to interact with key stakeholders and communicate feedback to the organization and a new direction for the launch.

Lastly, boards of first-time launchers can play a critical role in overseeing and approving the launch strategy. First-time launchers benefit from having biotech executives on their boards who have been on this journey before and can bring real-world experience and feedback to the management team.

2. Choose the optimal partnering strategy

The first step in developing a global partnering strategy is to quantify the magnitude of the product's commercial opportunity in major markets as well as the operational and capital requirements just for commercializing the product. A minimum revenue threshold must be established to offset the cost of entry and create value across each international market. Launch teams must identify countries meeting these thresholds early to prioritize countries worth pursuing through a direct model.

For orphan diseases and oncology niche indications with little competitive intensity and a modest level of required commercial investment, our close observation of first-time launchers shows that they can target 15 to 25 geographies where value is created on a go-it-alone basis. Direct geographic expansion in these markets also unlocks synergies with the U.S. and provides greater control over global branding and pricing of first-time launches.

However, a direct model is not without risks. Regulators in Europe often call for data from local clinical trials or real-world evidence, payers repeatedly place constraints on the pricing and reimbursement of approved drugs, and launch delays can be substantial. Importantly, executing concurrent launches across the U.S. and Europe presents operational challenges for centralized teams trying to provide as much support as they can abroad without disrupting execution of their U.S. commercialization plans.

Once decisions around international partnering have been made, first-time launchers can turn their attention to the U.S. commercial strategy. We found that many companies

created tremendous value by going it alone in the U.S., particularly for specialty markets requiring focused infrastructure that would be difficult to build and share with a partner.

For more complex markets with high barriers to entry, first-time launchers can opt for co-promotion agreements that allow them to leverage the existing capabilities and stakeholder relationships of a potential partner. This model can accelerate the first-product launch trajectory and reduce the investment burden and risk of going it alone. It also allows first-time launchers with deep pipelines to mobilize their resources to develop additional programs or prepare for future launches. That said, co-promotion requires strong capabilities in managing the partner relationship to circumvent governance complexities and lessen cost inefficiencies resulting from duplication of efforts.

3. Plan for sufficient capital formation

Companies preparing for a first product launch need to carefully manage the financing of multiple critical, costly priorities. That includes developing a compelling clinical plan for their first product, building a robust pipeline to lay the foundation for future growth and scaling up commercial operations to support the first launch.

Our analysis shows that first-time launchers often tend to underfund these priorities and underestimate their capital requirements. It is therefore critical for these companies to build clinical and commercial scenarios that account for regulatory delay, suboptimal labeling or unexpected competitive threat to their first product launch. A careful evaluation of cumulative cash requirements in a worst-case situation can help shape the financing strategy by informing choices between nondilutive upfront payments from partnership, dilutive secondary equity offerings or alternative financings such as synthetic royalty monetization. And in today's challenging environment, first-time launchers need to be more vigilant than ever in assessing these funding options and ensure they build a runway to long-term financial sustainability.

4. Manage investor expectations carefully

Armed with a deep knowledge of the product value proposition, first-time launchers must communicate their product differentiation in the market and ensure achievable revenue expectations on the part of investors. Overstating the magnitude of their product's commercial opportunity or allowing misguided Street projections to prevail can lead to short-term share price gains but quickly expose the company to valuation correction once their product starts missing consensus estimates.

Guiding investors on achievable revenue expectations is therefore a more prudent approach but a difficult one to manage. Biopharma leaders first need to be cautious about over-communicating to investors before launch. Assumptions to share externally include detailed clinical trial data, facts about disease epidemiology and comparative analysis of competitor product profiles. Beyond that, companies should be cautious about disclosing too many views on the anticipated revenue performance of their product. Instead, they should react in a subtle manner when needed to counter investors' presumptions. A recent example of such judicious intervention involves a first-time launcher that was exposed to investor overconfidence in the adoption of its first product and shared a range of ramp curves from analog products to set more realistic growth expectations.

Leaders who can execute on the right commercialization plan, make the optimal partnering decisions, secure adequate capital, and meet or exceed investor expectations will prosper through first product launch. Short of an exceptional product profile that can offset setbacks in planning, execution or communication, these four strategic levers are essential to the success of biopharma companies launching a first product.

For more information, please contact lifesciences@lek.com.

Endnotes

[1]Includes two companies that filed for bankruptcy in the 24 months post-first product launch

[2]Excludes two companies for which share price data was unavailable from S&P Global Market Intelligence

About the Authors

Pierre Jacquet
Pierre Jacquet, M.D., Ph.D., is a Managing Director and is Vice-Chairman of L.E.K.'s Global Healthcare Practice. Based in Boston, Pierre has more than 20 years of experience in corporate and business unit strategy consulting and in M&A advisory services. He has led numerous engagements across the biopharma, medtech and diagnostic sectors, helping companies identify and execute strategies that maximize shareholder value creation.

Jenny Mackey
Jenny Mackey is a Principal in L.E.K.'s Life Sciences practice and the Director of L.E.K.'s Healthcare Insights Center. In her role as a Principal, Jenny focuses on the biopharmaceutical sector and advises clients on a range of issues including R&D portfolio prioritization, new product planning, forecasting and valuation, and organizational performance and development. In the Healthcare Insights Center, she is focused on generating insights and thought leadership on topics and trends with major impact across the healthcare industry.

Hayley Tessler
Hayley Tessler is an Engagement Manager in L.E.K.'s Life Sciences practice. Hayley primarily focuses on the biopharmaceutical industry and has completed strategic engagements covering a range of issues, including market opportunity and landscape assessment, launch readiness and planning, commercial due diligence, and organizational design and strategy.

About L.E.K. Consulting
We're L.E.K. Consulting, a global strategy consultancy working with business leaders to seize competitive advantage and amplify growth. Our insights are catalysts that reshape the trajectory of our clients' businesses, uncovering opportunities and empowering them to master their moments of truth. Since 1983, our worldwide practice — spanning the Americas, Asia-Pacific and Europe — has guided leaders across all industries from global corporations to emerging entrepreneurial businesses and private equity investors. Looking for more? Visit **www.lek.com**.