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Biopharma Launch Trends — Lessons Learned From L.E.K.'s Launch Monitor

The cost of drug development continues to rise and the probability of creating new blockbuster therapies is not getting any easier. As a result, most biopharma companies focus primarily on how to efficiently develop product candidates with high commercial potential. However, a Food and Drug Administration approval is no guarantee of success; it is just the beginning. To drive real value, it is critical that biopharma companies execute the launch process flawlessly. As history shows, many companies fail in this process, due to a combination of factors such as limited market access, poor understanding of market needs or misjudgment of competitive threats.

L.E.K. Consulting's proprietary Launch Monitor provides a comprehensive look at the sales performance of U.S. biopharmaceutical launches going back to 2004. This includes more than 450 launches of new molecular entities. This tool enables analysis of launch trends over time as well as in-depth analysis of how performance, both absolute and relative to Street

consensus expectations, varies across different therapeutic areas, company types, product profiles, competitive dynamics and pricing bands.

Leveraging these data and analytics, L.E.K. supports biopharma companies launching new products, enabling greater value for patients, providers, payers and shareholders by applying key learnings from previous market launches.

A strong launch is critical to achieving maximum commercial potential

Looking back over the past 15 years, it is apparent that blockbuster products are rare. While the average peak U.S. revenue of products launched over that time is just over $800M, only one in five of these products reached U.S. sales of $1B, and this does not factor in the long list of candidates that failed in the clinic. More surprising, approximately 50% of all products launched over the past 15 years failed to reach peak U.S. sales of $250M (see Figure 1).

Stumbling out of the gate on a product launch can be challenging to overcome, especially as competition continues to intensify across most disease areas. On average, products will reach 50% of their peak sales by year three, and these early-year sales are strongly predictive of ultimate peak sales (see Figure 1). Some areas like oncology ramp even faster, reaching 50% of peak sales by the end of year two, further underscoring the importance of early launch performance.

Biopharma Launch Trends — Lessons Learned From L.E.K.'s Launch Monitor was written by **Peter Rosenorn**, **Pierre Jacquet** and **David Barrow**, Managing Directors, and **TJ Bilodeau**, Principal, in L.E.K.'s Life Sciences & Pharma practice. Peter, Pierre, David and TJ are based in Boston.

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Key findings

- The average peak U.S. revenue of products launched over the past 15 years is about $800M, with only one in five reaching U.S. sales of $1B, and over half failing to reach peak U.S. sales of $250M

- On average, products reach ~50% of peak sales by year three, and these early-year sales are strongly predictive of ultimate peak sales

- About half of all products launched over the past 15 years have underperformed pre-launch consensus forecasts by more than 20%

- While performance issues cut across all therapeutic areas, infectious disease, immunology and cardiovascular diseases are the therapeutic areas where the most products underperform Street expectations

- On average, large pharma companies' product launches have average peak revenues 50% higher than those of smaller players

- Small companies were also more likely to underperform expectations than larger companies, and this

difference in revenue performance is magnified in diseases driven by primary care channels

- Early launch planning, effective stakeholder engagement, better forecasting and highly disciplined execution can help address barriers and better manage the Street's expectations

For an explanation of the L.E.K. Launch Monitor's methodology and key definitions, please refer to page 5.

Only half of all product launches meet or exceed the Street's expectations

Even after a product gets through the clinic, one thing that becomes clear is that achieving the Street's expectations is a significant challenge. Most market observers agree that the accuracy of analyst forecasts is spotty, especially when products are still in development and clinical profiles are more uncertain.
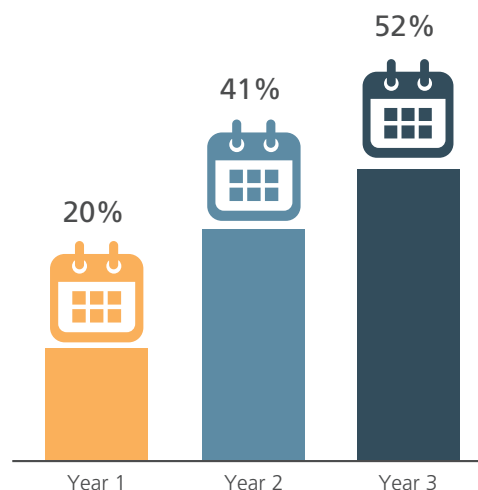
As a result, any gap between Street expectations and actual performance is likely driven in part by the lack of precision in these analyst forecasts. However, even when looking at consensus forecasts just prior to launch — forecasts that are heavily informed by expected product labels and management expectations — 40% of products underperform Street forecasts by more than 20% (see Figure 2).

Figure 1
Peak revenue and ramp to peak sales of U.S. product launches

Peak year revenue of product launches (2004-16)*
Percentage of products in each revenue bucket

- 5% >$3B
- 19% $1B-$2.99B
- 14% $500M-$999M
- 17% $250M-$499M
- 46% <$250M

Total
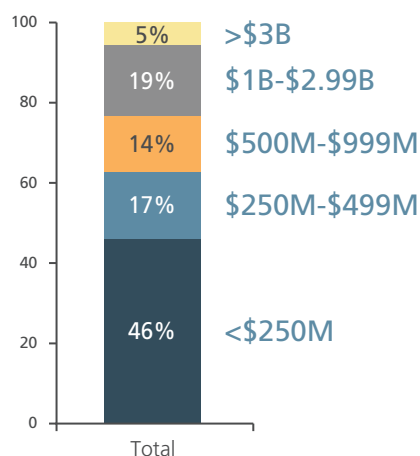
Ramp to peak in years 1-3 post-launch
Percentage of peak year revenue

- Year 1: 20%
- Year 2: 41%
- Year 3: 52%

*Products reaching peak volume in 2018 leverage forecasted revenue and pricing for ramp speed and peak year revenue analysis
Source: L.E.K. Launch Monitor, EvaluatePharma

Figure 2

Products where actual performance is less than 80% of forecast performance by therapeutic area (2004-16)*

Percentage of products that underperformed in years 1-3 post-launch

Total new molecular entity launches by therapeutic area (2004-16)

Therapeutic area	Percentage underperformed	Total NME launches
Cardiovascular	50%	28
Immunology	50%	14
Infectious disease	48%	62
Oncology	38%	82
CNS	34%	41
GI/metabolic	34%	52
Hematology	25%	28

> Across all launches in this period, an average of ~**40%** underperformed their forecast by >20%

*Other areas that feed total average include Genitourinary, Respiratory, Derm, Musculoskeletal, Sensory, Rare Diseases, Hormonal
Source: L.E.K. Launch Monitor

This is especially true in the first few years after launch, when meeting unrealistic Street expectations can be challenging. Analysis of the past 15 years shows that more than 90% of products have U.S. revenue less than $250M in year one and more than 70% have revenue less than $250M in year two. Since the negative impact of missing a forecast can be severe, particularly for a small biotech launching a first product, companies must be cautious when providing revenue guidance and managing expectations from the Street.

While performance issues affect all therapeutic areas, they are worse in areas like infectious disease, immunology and cardiovascular disease, where about 50% of products underperform launch expectations by more than 20%. Whether it is underestimating the challenge of educating and changing the prescribing behavior of a large and disparate group of physicians, or misjudging some of the logistical and/or economic barriers that may be more prevalent in these areas, it appears that products targeting larger, more diffuse call points are more likely to underperform than those targeting focused, specialty call points.

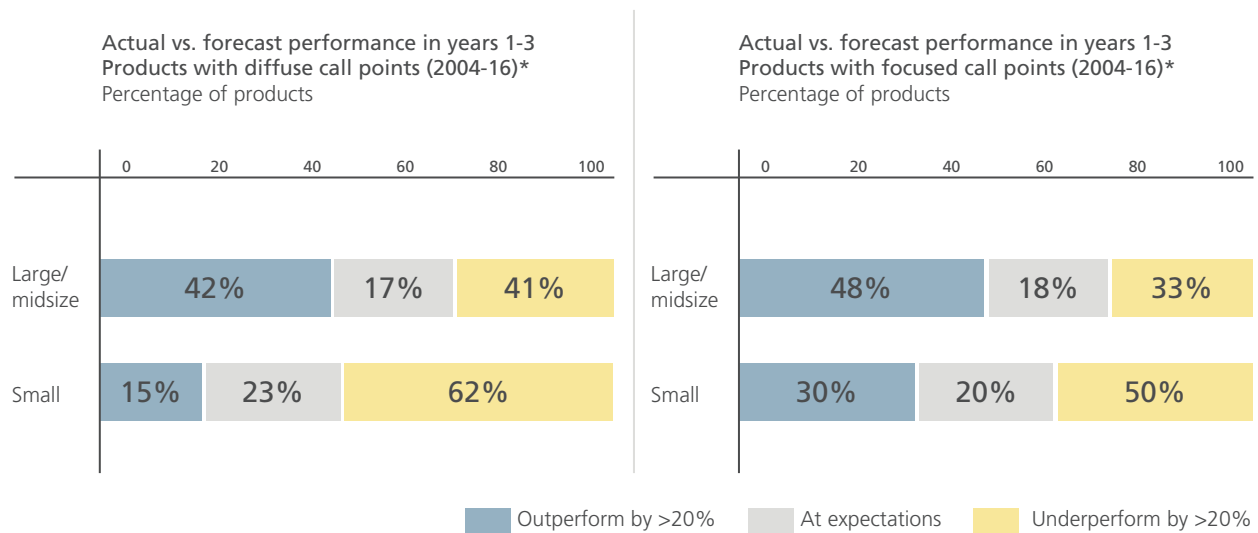## Size matters for commercialization

Shifting the lens from disease area to company scale reveals some similarly interesting insights. L.E.K.'s experience has shown

that small biopharmas are better equipped than their larger brethren to innovate and develop first- or best-in-class products, originating more than 50% of innovative products. However, where size, scale and institutional knowledge can be a barrier to innovative R&D, they become key enablers when it comes to the commercialization and life cycle management of a new pharmaceutical product.

Given big pharma's propensity to disproportionately acquire assets with the greatest revenue potential, it might not be a surprise that average peak revenue for products launched by big pharma is 50% higher than the average peak for products launched by smaller players. What is more insightful is that even after normalizing for product expectations, small companies were more likely to underperform expectations than their larger counterparts. This delta in performance versus expectations is magnified in disease areas with larger, less well-defined call points (see Figure 3).

This analysis is aligned with prior L.E.K. research showing that only a small percentage of emerging biopharma companies launching their first product exceeded analyst sales expectations, highlighting how challenging commercial execution can be for smaller companies embarking on their first launch.

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Figure 3
Actual performance relative to Street expectations by call point and company scale

Actual vs. forecast performance in years 1-3
Products with diffuse call points (2004-16)*
Percentage of products

	Outperform by >20%	At expectations	Underperform by >20%
Large/midsize	42%	17%	41%
Small	15%	23%	62%

Actual vs. forecast performance in years 1-3
Products with focused call points (2004-16)*
Percentage of products

	Outperform by >20%	At expectations	Underperform by >20%
Large/midsize	48%	18%	33%
Small	30%	20%	50%

Legend: ■ Outperform by >20% ■ At expectations ■ Underperform by >20%

*Call point characterization based on level of primary care physician involvement in treatment and prescribing decisions for that disease
Source: L.E.K. Launch Monitor

Early launch planning can help overcome adoption barriers and manage analysts' expectations

So what does all this mean for biopharma companies preparing for an upcoming commercial launch? From our experience working across a wide variety of launches, L.E.K. has distilled a few key launch perspectives:

- **Plan the launch early and monitor:** Even for companies with great products, a lack of launch preparation can lead to performance challenges. We recommend that biopharma companies start thinking about launch planning up to 36 months prior to first market authorization. It is also critical to ensure that a cross-functional team is in place to support and track the myriad things that are important for a successful launch. Additional L.E.K. perspectives on essential factors for a successful launch can be found here.

- **Be realistic about the launch challenges:** As a part of the process, biopharma executives need to think critically about the barriers to uptake, especially within some of the larger primary care or hospital-focused indications. Pricing and reimbursement pressures, access to key stakeholders, and competitive pressures vary widely across indications and therapeutic areas and can significantly impact the scope and pace of adoption.

- **Carefully consider partnership:** Smaller companies have been less successful than large companies when launching pharmaceutical products, given their limited resources and capabilities. It is important for biopharma executives to think strategically about commercialization choices and carefully evaluate partnership opportunities. Additional L.E.K. perspectives on partnership decisions can be found here.

- **Manage investor expectations:** Biopharma companies should thoroughly examine forecast assumptions and solicit external expert opinions where relevant to manage investor expectations toward realistic and achievable goals. Small overstatement of the addressable patient population, misjudgment of market access levels or mischaracterization of emerging competitive dynamics can throw off a forecast considerably and misalign market expectations as well as launch planning efforts.

For more insights on biopharma launch performance or to hear more about how you can optimize your upcoming launch, please reach out to us at lifesciences@lek.com and we would be pleased to arrange a meeting.

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L.E.K. Launch Monitor methodology and key definitions

- The L.E.K. Launch Monitor includes **over 450 launches** of new molecular entities, and analyzes U.S. sales performance of these launches

- **No reformulations** are included in the analysis, and only products **launched through 2016** are included in longitudinal and/or peak year analyses

- **Peak revenues** are defined as the maximum annual revenue for a product between launch year and 2025; actual data is used for 2004-19 and EvaluatePharma forecast sales are used for 2020-25, providing a minimum of 10 years of sales data for all products included in the analysis

- **Consensus analyst forecasts** were pulled from EvaluatePharma at or as close to launch as possible

- When comparing performance relative to analyst expectations:

  o **"Underperformance"** is defined as actual cumulative sales in years one to three that are less than 80% of expected cumulative sales over that three-year period

  o **"Outperformance"** is defined as actual cumulative sales in years one to three that are greater than 120% of expected cumulative sales over that three-year period

  o **"At expectations"** is defined as actual cumulative sales in years one to three that are between 80% and 120% of expected cumulative sales over that three-year period

- When defining company size:

  o **Small companies** are those with market caps of less than $5B at launch

  o **Midsize companies** are those with market caps between $5B and $40B at launch

  o **Large companies** are those with market caps of greater than $40B at launch

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About the Authors

Peter Rosenorn is a Managing Director and Partner in L.E.K.'s Boston office and co-leads the firm's life science launch excellence efforts. Peter has a focus on growth strategy and organization and performance, and he advises clients on a range of critical business issues, including organizational scale-up and development, launch planning and commercialization, transaction support, forecasting and valuation, and post-merger integration.

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.

David Barrow is a Managing Director and Partner in L.E.K.'s Boston office and is the former Head of the U.S. Healthcare Practice. David has more than 20 years of experience in consulting at L.E.K., including corporate strategy development, M&A support and global commercial planning. He has worked on more than 500 assignments with over 200 clients in a variety of sectors, including pharmaceuticals, biotechnology, medical devices and diagnostics.

TJ Bilodeau is a Principal in L.E.K.'s Boston office and a member of the firm's Life Sciences practice. TJ has more than 15 years of experience supporting clients across the life sciences industry with a focus on growth strategy for emerging and midsize biopharma companies. During his career, he has worked across several therapeutic areas and has extensive experience in commercialization strategy, portfolio optimization and transaction support.

About L.E.K. Consulting

L.E.K. Consulting is a global management consulting firm that uses deep industry expertise and rigorous analysis to help business leaders achieve practical results with real impact. We are uncompromising in our approach to helping clients consistently make better decisions, deliver improved business performance and create greater shareholder returns. The firm advises and supports global companies that are leaders in their industries — including the largest private- and public-sector organizations, private equity firms, and emerging entrepreneurial businesses. Founded in 1983, L.E.K. employs more than 1,600 professionals across the Americas, Asia-Pacific and Europe. For more information, go to www.lek.com.

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