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Biopharma Operational Scale Up for First Product Launch: Planning for Successful Execution in Challenging Times

As new products receive approval from the Food and Drug Administration, an increasing number of biopharma first-timers are joining the ranks of established, fully integrated drug companies. For a biopharma organization that has spent years focused on research and development, this transition can be challenging, even when the executives individually have significant launch experience from other companies.

Within a relatively short amount of time, biopharma organizations have to make difficult choices about scaling up the enterprise and customizing the operational model to ensure a successful first product launch. R&D-focused biopharma organizations with head counts in the range of 30-70 employees have to transform into fully integrated organizations three to five times their size by the time of product launch two to three years later (see Figure 1).

Besides the substantial recruiting of new talent in a short period of time, executives need to complete a broad range of operational activities and make an endless number of decisions within a complex ecosystem of internal stakeholders as well as external customers, investors and potential partners. L.E.K. Consulting's experience with more than 30 companies that have pulled through this inflection point suggests that these operational challenges resulted in launch miscues and ultimately revenue shortfalls.

To provide perspective on lessons learned from biopharma companies that have successfully transformed into commercial organizations, this article defines some of the key principles biopharma executives should bear in mind as they scale up their organizations. It outlines L.E.K.'s proprietary approach to enabling enterprise readiness, allowing the management team to deliver it expertly at corporate and functional levels, while developing a culture and supportive processes for high performance.

Retaining partial or full ownership of first product

The level of retained ownership of the first product is the foundational step in addressing the need and scale of the biopharma operational model. Companies that opt for monetizing their lead asset against up-front payments, milestones and royalties benefit from short-term risk mitigation, financial flexibility and the operational leanness of this model. Enterprise scale up is less complex in this case, as the company skills and capabilities remain focused on R&D.

However, out-licensing commercial rights of the first product to a partner does not provide biopharma companies and their shareholders with the long-term upside of partial or full product ownership. The more rights a company keeps, the more control it

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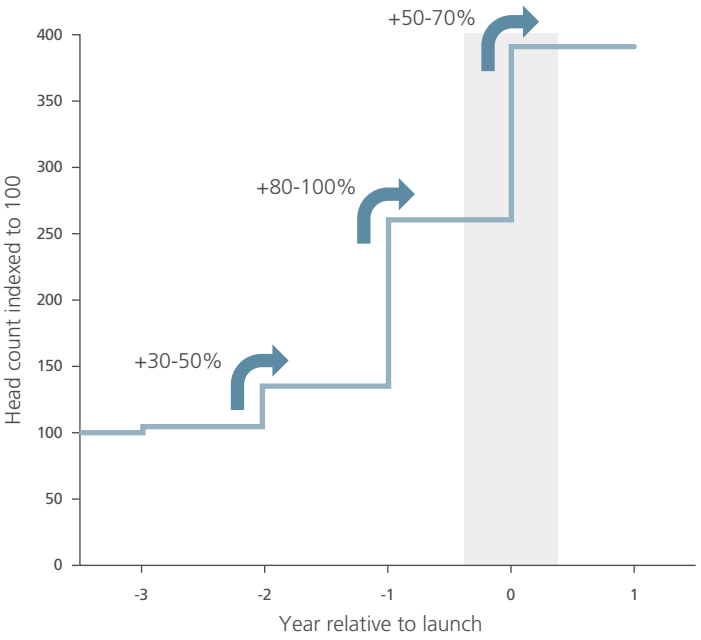
Figure 1
Operational scale-up before first product launch



Note: Based on analysis of 23 biopharma companies with launched products in 2010-2014
Source: L.E.K. analysis

maintains around the commercialization of its asset. Further, building direct relationships with customers through a commercial organization provides biopharma companies with important market insights that shape critical decisions such as product life cycle management and R&D portfolio prioritization. Forward integration also provides companies with insights and fully integrated capabilities to win future business development opportunities by commercializing in-licensed or acquired assets. Last and most important, companies that retain commercial rights capture a bigger share of their product revenue and profit, generating incremental shareholder value through higher trading multiples.

In the past decade, most U.S. biopharma companies have opted for significant retained ownership of their first product in some regions of the world. Supporting our findings is a proprietary L.E.K. database that tracks the development and commercial path of drugs originated by U.S. biopharma companies and approved by the FDA and/or the European Medicines Agency (EMA) between January 2005 and December 2015.

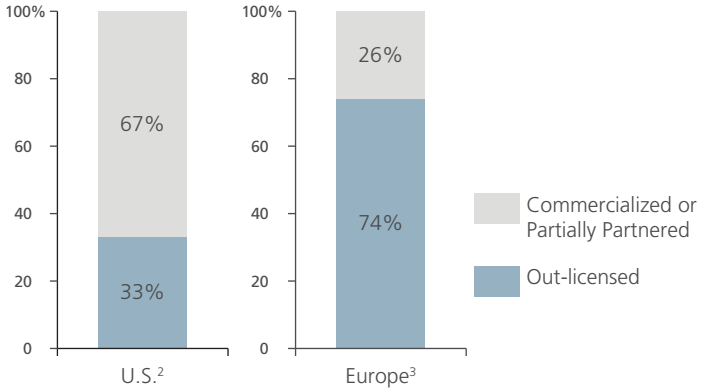
During this period, 96 U.S. biotech companies had a product approved for the first time by the FDA and/or the EMA. Two-thirds of these companies took an active role (either alone or with a partner) in commercializing their first drug in the U.S. In contrast, only a quarter of the companies with a first product approved in Europe participated in the product launch in this region (see Figure 2). The burden of European infrastructure requirements and the potential operational distraction from the U.S. launch were often considered key hurdles to European forward integration. Almost all companies that opted for going it alone in Europe concentrated their efforts on favorable market conditions of an orphan indication with a focused ecosystem of stakeholders and a relatively low barrier to entry.

In short, the dominant engagement model by U.S. biopharma companies has been to retain full or partial ownership of their first product in the U.S. and (for non-orphan companies) to let an established partner with commercial infrastructure lead the product launch outside the U.S. Finding the right balance of forward integration around a first product launch is a difficult choice biopharma executives must make at the outset, with the right decision resting between long-term value creation of retained ownership and short-term operational risk of sequential launches across multiple regions.

Customer-facing model design as key gating factor

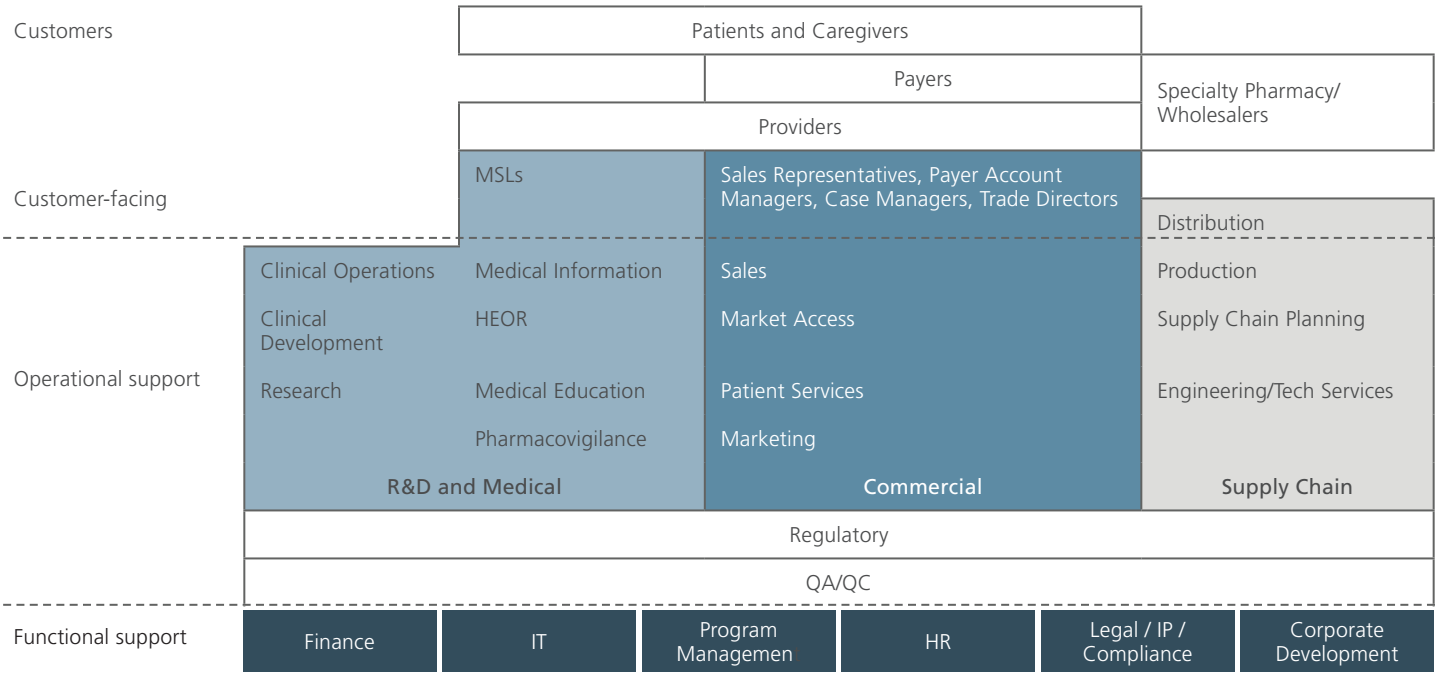
Once the decision is made to retain full or partial commercial rights of the lead product, biopharma executives need to identify the optimal commercial model for the product, defined as the organizational makeup, people, process and technology that companies need to develop or acquire for addressing customer

Figure 2
Engagement models in the U.S. and Europe for first product launch[1]



Notes: [1]Drugs developed by U.S. biopharma companies and approved by FDA and/or EMA (n=96) Jan. 2005 – Dec. 2015, [2](n=94), [3](n=43)
Source: L.E.K. analysis

Figure 3
Customer-oriented operating model



Source: L.E.K. analysis

needs in markets where commercial rights have been retained. This decision is a key trigger for scaling the overall enterprise, as related functions such as HR, IT, compliance, manufacturing, supply chain and others will have to scale in accordance with the size and design of the commercial organization.

When designing the commercial model, companies should first develop a common point of view on how the size of the addressable market, the complexity of the product stakeholder ecosystem, and the key market dynamics will shape the breadth and structure of the customer-facing activities (see Figure 3). Executives need to consider critical market dynamics such as the decreasing productivity of the traditional sales reps channel, the already-increased influence of payers in the stakeholder ecosystem, the market fragmentation into orphan or specialty niches due to the targeted nature of innovative therapies, and the emergence of new technologies surrounding key treatment and adherence choices.

Next, the commercial model needs to leverage customer-facing functions to engage the entire network of customers and address their critical needs through a compelling product offering. Key responsibilities and skills of each customer-facing role need to be outlined, and key decisions around which activities should be field- versus office-based must take place. Medical Scientific Liaisons (MSLs), sales representatives and managed care account managers are the most common field-based roles, but many customer-facing activities now include patient reimbursement and support roles for nurses.

Once the customer-facing functions have been defined, it is critical to ensure that the commercial model can deliver operational efficiency and effectiveness through integrated processes that link commercial functions to supporting functions. This integration relies on cross-functional interdependencies that will be described later. Equally important is the capacity of the selected commercial model to adapt to the evolving market environment. Successful commercial models eventually rely on biopharma executives' propensity to continually adjust the design of their commercial model and respond to the changing influence patterns and needs of their customers. Steps toward an integrated, flexible and agile commercial model are decisive milestones in scaling up the biopharma enterprise and launching the first product.

Developing the underlying enterprise model

Once the commercial model has been conceived, biopharma executives need to turn their attention to the overall enterprise model. It should be designed to ensure flawless execution of the first product launch while continuing the expansion of underpinning R&D activities.

In developing the enterprise model, it is important to align the organization along core corporate ground rules. These can be grouped into key business principles such as how risk-willing the company is, how decentralized the investment decisions should be, what level of outsourcing is optimal, or what type of organizational structure (single versus dual reporting) best fits the operational requirements.

The enterprise model also needs to focus on the development of disciplined mechanisms to enable efficient interactions between functions. Each function needs to first develop a list of key activities that must be achieved for a successful product launch. Activities that require input and decision-making from stakeholders of different functions should then be compiled and categorized as cross-functional interdependencies. Tools and processes can then be deployed to integrate different functional activities into the management and execution of the enterprise scale up. Examples of tools and processes range from the development of standing cross-functional teams to the creation of automated planning templates that enable functions to track each other's activities for coordination (see Figure 4).

L.E.K.'s experience indicates that mapping and addressing these interdependencies early in the design of the enterprise model can help avoid delays in the timing of key deliverables (e.g., publications not ready in time for launch support), limit overlaps between activities (e.g., duplication of training and market intelligence efforts) and maximize the quality of decisive outputs (e.g., ensure cross-functional input to label development).

Finally, the leadership team needs to determine the right level of outsourcing for the enterprise model. Biopharma companies preparing their first launch are most often under pressure from investors to contain fixed costs and outsource activities to gain knowledge, perform certain activities and solve problems. As these companies engage with their network of providers, they must maintain control over the work outsourced, as operational efficiency can be achieved only through constant communication, complete transparency and frequent exchange of information with external parties. These strategic relationships require considerable time to manage, and simple outsourcing contracts with clear and focused deliverables should be given preference. Any setbacks in outsourcing can lead to trial delays and cost overruns that cannot be withstood.

Figure 4
Tracking tools for enterprise readiness

Source: L.E.K. Consulting

Winning strategies

A closer look at L.E.K.'s experience in supporting biopharma first product launches offers some insightful lessons on successes and pitfalls of enterprise scale up:

1. Scale the enterprise to a reasonable and achievable steady state of business. Gaps between internal-lead product forecasting and bullish sell-side analyst revenue estimates are prevalent among public biopharma companies launching their first product. Too many companies rely on external projections to inform their own forecast and guide strategic decisions for scaling up their enterprise model. Unfortunately, consensus forecasts are often inaccurate and overly optimistic by more than 100% of actual revenues. Biopharma executives therefore need to set up a reasonable and achievable internal target on the magnitude of revenues they can generate and the resulting level of human resources and capabilities needed to achieve their goal.

Finding the right balance in ramping up to a steady state solution lies in being judicious with resource and capital allocations by investing early enough to deliver on the product launch and

market ramp-up while not overinvesting when risk, cash and shareholder dilution are potential constraints. Executives need to stage their enterprise scale up and related investments along "trigger points," such as phase III data read-out, filing, approval and launch, and be prepared to invest at risk in certain areas along the long road to product approval.

2. Retain an entrepreneurial and collaborative culture. Fostering a creative mindset that rewards entrepreneurial spirit and accountability at corporate, functional and individual levels is another priority for biopharma executives. Enterprise scale up and its underlying processes can trigger situations where functions and geographies do not always share information effectively with others, which undermines overall enterprise readiness. Silos can emerge within different layers of the organization, employees may become frustrated with each other, and simple tasks that would be accomplished swiftly can take a long time to resolve.

Biopharma companies must stay alert for these inefficiencies and create solutions that can be executed quickly without disrupting the product launch. An effective enterprise model can then flourish by striking a balance between an efficient process-driven organization and an entrepreneurial and accountable culture.

3. Plan for delays without losing confidence and momentum. Anyone who has been part of launching a product knows that something challenging or unanticipated will happen along the way. Slower-than-planned trial enrollment, unexpected regulatory requirements and supply chain issues are common setbacks. While biopharma companies need to move forward and execute with confidence on a best-case plan, they should understand where the risks lie, monitor these events and develop contingency plans in advance to put the enterprise scale up back on track.

Conclusions

Scaling up the operation of a biopharma company for first product commercialization requires focus and commitment. It is critical that biopharma companies plan their operational scale up and enterprise readiness well ahead of approval. The road to first product launch will be demanding, but armed with insights from this article and executive commitment, biopharma companies can scale the enterprise to ensure successful first product commercialization and deliver superior shareholder value.

Suggested readings

"Biopharma: Beyond the First Product." *In Vivo*, June 2006.

"Outsourcing From a Small Pharma Perspective." *Pharmaceutical Outsourcing*, November 2014.

"The Silo Mentality: How to Break Down the Barriers." *Forbes*, October 2013.

About the Authors

Pierre Jacquet is the Global Head of the Biopharmaceuticals & Life Sciences practice and a Managing Director and Partner in the Boston office. He is also a member of L.E.K.'s Global Leadership Team. Dr. Jacquet has more than 20 years of experience in corporate and business unit strategy consulting, R&D portfolio management and mergers and acquisitions advisory services. He has assisted clients with issues such as strategic opportunity evaluations, product prioritization, product planning and commercialization, strategic partnering, strategic activation, and mergers and acquisitions.

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