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Biopharma Operational Scale-up for First Product Launch: 7 Hazards to Avoid

Scaling up to launch the first product is one of the most challenging transitions for a biopharma organization as the leadership team prepares to grow an R&D-focused company with 30 to 70 employees into a multidimensional organization three to five times larger, usually adding new functions, sites and geographies.

In a prior *Executive Insights*, Biopharma Operational Scale-up for First Product Launch: Planning for Successful Execution in Challenging Times, we covered several key principles that biopharma leaders should consider as they prepare for scale-up. These include deciding the level of retained ownership of the first product in each geography, identifying the optimal commercial model for that product, and developing the underlying enterprise model that enables customer-facing functions to build and execute the launch plan, while simultaneously continuing R&D expansion.

In this *Executive Insights*, L.E.K. Consulting has identified seven hazards that could derail a strong launch, for instance:

- Missing commercial and medical input on pivotal trial design may limit the ability to reach market access and pricing expectations
- Failure to invest in a well-defined manufacturing and logistics strategy can be a launch-killer for biopharmas with novel and complex modalities, e.g., gene-based therapies
- Underinvesting in back-office functions is penny-wise but pound-foolish, as it may lead to launch delays if critical staff cannot be hired and onboarded on time

Time and again, one of the most important lessons we have learned is to start cross-functional launch planning and readiness activities early, preferably up to three years before launch. A key part of a successful launch is a well-prepared organization, and we have drawn upon our experience working with biopharma companies navigating this critical transition to highlight seven specific scale-up hazards that executives should avoid as they prepare for launch (see Figure 1). We indicate where they are most relevant within the customer-facing operating model, and we close with a set of key questions that management could use to self-assess whether their organization's scale-up activities are on track.

Seven hazards to avoid

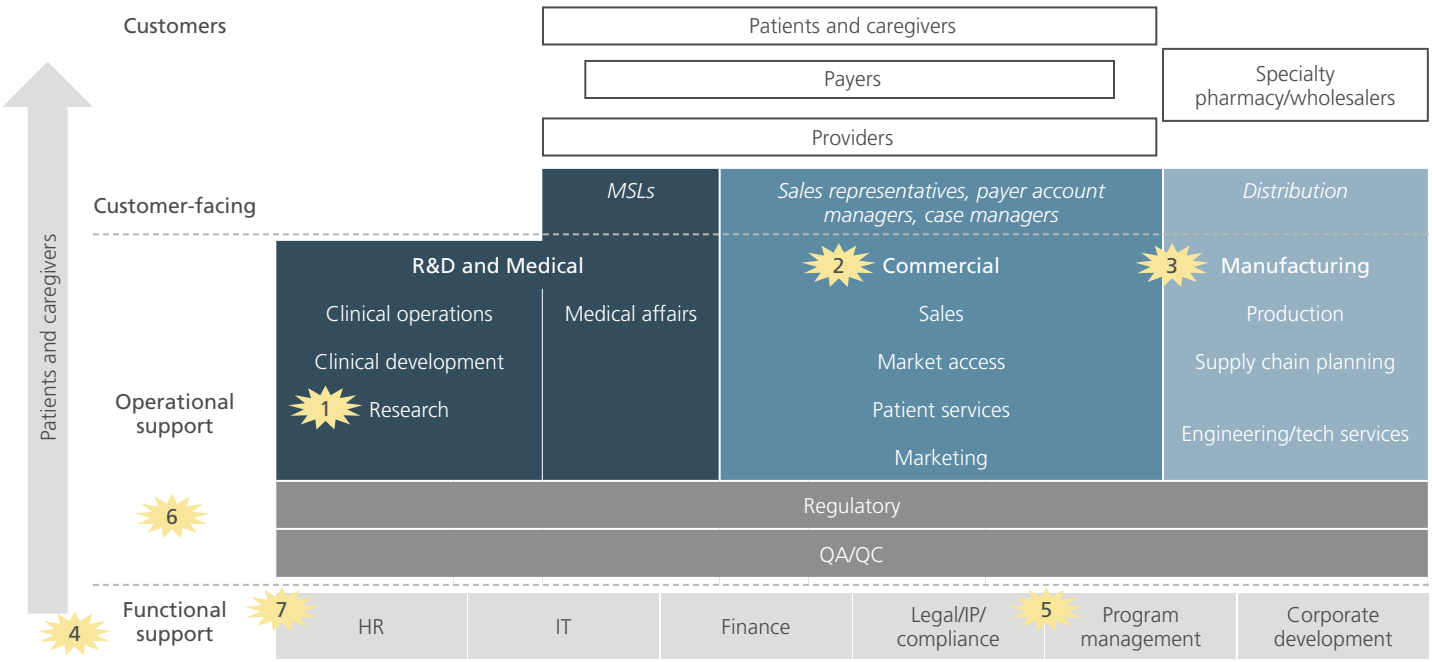
1. Leaving research behind

When significant cash is needed prelaunch for investments in pivotal trials and for building out the manufacturing and commercial functions, research is often an area that feels investment-constrained. Companies must walk the fine line between going "all hands on deck" for their first launch and ensuring that the

Biopharma Operational Scale-up for First Product Launch: 7 Hazards to Avoid was written by **Pierre Jacquet** and **Peter Rosenorn**, Managing Directors, and **Aditya Natarajan**, Consultant, in L.E.K. Consulting's Life Sciences & Pharma practice. Pierre, Peter and Aditya are based in Boston.

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

Figure 1
Customer-facing operating model with 7 common scale-up hazards



discovery engine has sufficient resources to continue to fill the pipeline. While there are no easy solutions, management should ensure that a systematic portfolio prioritization and stage-gate framework are in place to make investment trade-offs that ensure research investments are considered through the lens of long-term corporate growth as well as near-term cash requirements.

2. Missing commercial and medical input on pivotal trial design

Emerging biopharmas typically establish the core commercial and medical functions after pivotal trials are already underway. By waiting this long, companies risk missing out on informing clinical development plans with a robust market understanding, including who their key customers are, what trial endpoints and comparators are most meaningful to drive adoption, and how U.S. and non-U.S. pricing and market access negotiations can be best supported by trial evidence. Management should consider onboarding a handful of core marketing, market access and medical affairs team members prior to designing pivotal trials and incorporate findings and feedback from their efforts into the pivotal trial design.

3. Delaying clinical and commercial manufacturing scale-up

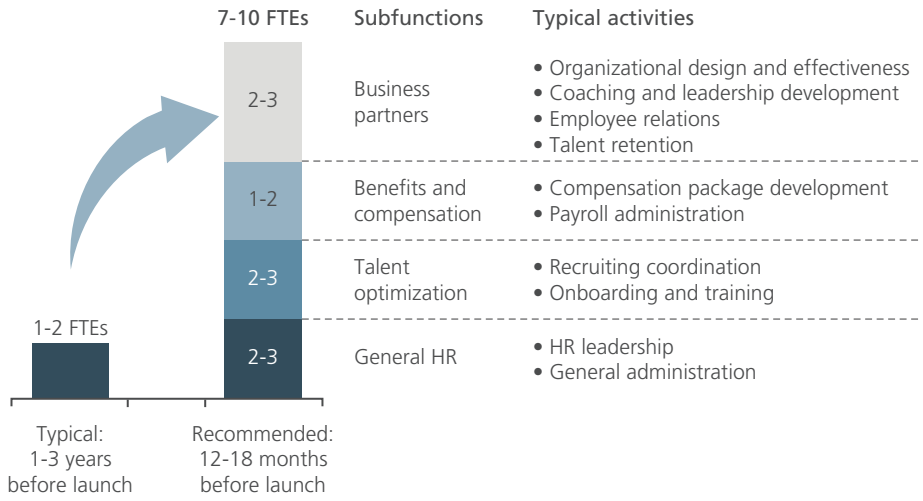
Establishing a validated supply chain for GMP-grade drug products and drug substances is a necessary condition for late-stage clinical trials and filing, and doing so can take years. This is becoming increasingly critical as biopharmas launch novel therapeutic modalities. For example, viral vector manufacturers have been identified as a bottleneck for gene therapy commercialization, requiring several years' lead time for process development and scale-up. While not all such challenges can be foreseen, management should ensure that manufacturing timelines are developed sufficiently in advance and incorporated into clinical development, filing and launch plans.

4. Underinvesting in back-office functions

While companies know they need to build clinical, medical and commercial functions prior to launch, back-office functions such as HR, IT, legal and finance are commonly overlooked. Delaying their build-out can result in process inefficiencies that can compound to threaten the launch if not addressed quickly. For example, recruiting and onboarding of talent can slow down critically without sufficient HR resources.

Figure 2 shows how the HR function typically should scale up to meet the needs of the growing organization. Another example is that enterprisewide software decisions cannot be made efficiently without an adequately staffed IT department.

Figure 2
Example of required prelaunch back-office function growth: HR



5. Neglecting program management

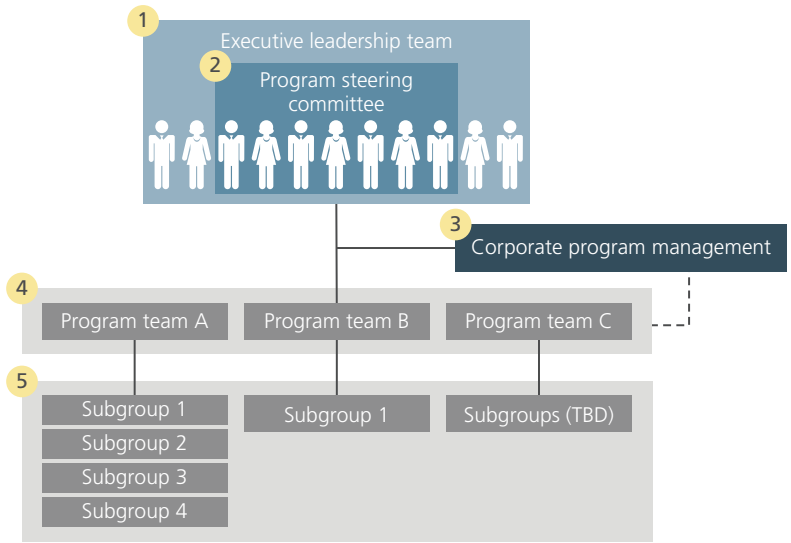
Strong program management is critically important to drive cross-functional collaboration and streamline tasks by development program to limit functions operating in silos. While project managers often exist in R&D, as assets advance through clinical development and show commercial potential, it is important for a companywide program management function to be formed to facilitate cross-functional alignment and manage the interface between executive leadership and each program team.

Our perspective is that program management should report to a corporate executive leadership team (ELT) member, potentially the CEO, to ensure that the function is perceived as objective and empowered by leadership. Without such empowerment, functional leaders may not take program managers seriously, preventing them from effecting change and holding individuals accountable. Effective program management requires senior leadership to buy into its importance and to emphasize that importance in companywide communications. Figure 3 presents an example of a governance structure with corporate program management liaising between individual program teams and executive leadership.

6. Unclear governance and reporting structures

As a biopharma scales up, new functions are typically established by hiring VP- or other executive-level individuals who then go on to build out those functions. This growth in management means that a relatively flat reporting structure — which may have worked for the ELT when the organization had 30 to 60 full-time equivalents (FTEs) — may not be as effective as headcounts

Figure 3
Example of governance structure with centrally reporting program management



1. **ELT:** Focuses on corporate strategy, setting priorities and monitoring cross-functional execution
2. **Program steering committee:** Subset of ELT members focused on providing guidance to program teams on regulatory strategy, clinical trial design, etc.
3. **Corporate program management:** Serve as facilitator between steering committee and program teams, and gain alignment with functional heads
4. **Program teams:** Oversee program execution and provide platform for alignment on issues not requiring functional head input, e.g., clinical protocol review, trial product supply
5. **Program team subgroups:** Plan and execute activities relevant to a subset of functions, e.g., NDA development, packaging; escalate issues when required

Figure 4
Organizational scale-up self-assessment

Scale-up status questions		"All set"	"OK"	"Work to do"
1.	Have the go-to-market strategy and customer-facing model been clearly defined and socialized with the ELT and board?			
2.	Do we have a process to systematically make investment trade-offs that ensure long-term growth?			
3.	Are the pivotal trials designed to support pricing and reimbursement, not just approval?			
4.	Are commercial-scale manufacturing timelines established and on track?			
5.	Does our scale-up plan explicitly incorporate back-office needs (e.g., HR, IT, legal and finance) to support the rest of the company?			
6.	Does our program management function drive programs forward with cross-functional input, on time and on budget?			
7.	Are our governance structure and processes well-understood throughout the organization?			
8.	Are we on track with hiring of critical talent?			

quadruple or more over two to three years when initiating pivotal trials and preparing to launch. To minimize costly overlaps and gaps, the ELT needs to review and evolve organizational responsibilities, reporting hierarchies, and governance structures as the company reaches growth inflection points.

7. Insufficient time to hire key talent

Companies are often behind their hiring timelines because finding the right talent in competitive markets usually takes much longer than expected. In particular, companies preparing to launch their first product may not be well-known or could be seen as less attractive to high-quality yet risk-averse candidates. Management would be wise to build in sufficient buffer time and start recruiting for required positions at least three to six months in advance, and even more for executive roles like chief commercial officer or specialized roles in such areas as quality, regulatory, biostatistics and pharmacovigilance.

Keeping track: Pointers for self-assessment

We close with a few questions based on these scale-up hazards that senior leadership can use to self-assess whether their organizations are on track (see Figure 4). While there are many key questions for management to consider, it is our experience that failure to address these seven potential hazards creates significant obstacles to a successful launch on time and on budget. Preparing to commercialize the first product is one of the most challenging moments in a biopharma company's evolution, but having executive leadership that is committed to the launch, is well-informed about potential roadblocks and possesses the right tools to address the issues is foundational to preparing the organization for success.

For an informal discussion of your scale-up situation, please feel free to contact us at **p.jacquet@lek.com** or **p.rosenorn@lek.com**.

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About the Authors

Pierre Jacquet is a Managing Director and Global Head of L.E.K.'s Life Sciences practice. He is also a member of the firm's Global Leadership Team. 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.

Peter Rosenorn is a Managing Director and Partner in L.E.K. Consulting's Boston office. He joined L.E.K. in 2010 and specializes in the Life Sciences & Pharma sector, with a focus on growth strategy and organization and performance. Peter 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.

Aditya Natarajan is a Consultant in L.E.K. Consulting's Boston office. Aditya is focused on L.E.K.'s Life Sciences & Pharma practice, with extensive experience with clients in the pharmaceuticals, research and diagnostics spaces. His work has spanned therapeutic areas such as oncology, hematology and rare diseases, and across service lines such as growth strategy development, organizational scale-up and M&A/transaction support.

About L.E.K. Consulting

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