EXECUTIVE INSIGHTS

From Discovery to Launch: Building Next-Generation Investment Governance for Biotech

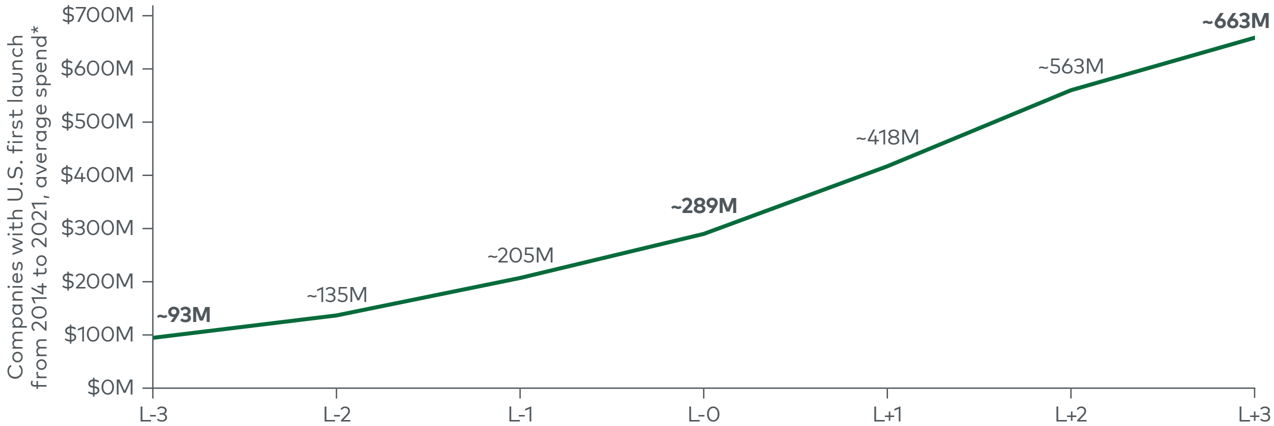
Emerging biopharma companies face a dual investment governance challenge as they scale up for first launch. Operating expenditures rise sharply, and the number of investment choices multiplies. These dynamics raise the bar for disciplined investment processes and governance, requiring leaders to separate the baseline from the incremental investment choices, compare options that pay back on different timelines, and make decisions in a timely and disciplined manner.

This edition of L.E.K. Consulting's *Executive Insights* offers a practical approach to framing investment trade-offs with concise actions to strengthen the operating model behind investment decisions.

Investment expansion around first launch

The move from clinical stage to commercial stage represents a profound step change in the scale and complexity of investment. Across roughly 85 biopharma companies that launched their first product in the U.S. between 2014 and 2021, average operating spend rose from about $90 million three years before launch to roughly $650 million to $700 million three years after launch, representing more than a sixfold increase, with approximately $2.4 billion in cumulative spend across that window (see Figure 1).

Figure 1
OpEx spend as emerging biopharmas launch first product



Average cumulative spend	~$93M	~$228M	~$433M	**~$722M**	**~$1.1B**	**~$1.7B**	**~$2.4B**
Number of companies	82	82	82	**77**	**69**	**61**	**54**

*Spend over time based on average spend across companies that launched their first product between 2014-2021. Spend represented in the analysis is not adjusted for inflation (i.e., a representation of actual company spend at the time of investment). The analysis includes 82 companies 3-years before launch to 54 companies that persisted to 3-years post-launch with several dropping off due to getting acquired (26 companies) or dissolving (2 companies).
Note: OpEx=operating expenditure
Source: Company websites; earnings calls; 10-Ks; L.E.K. research and analysis

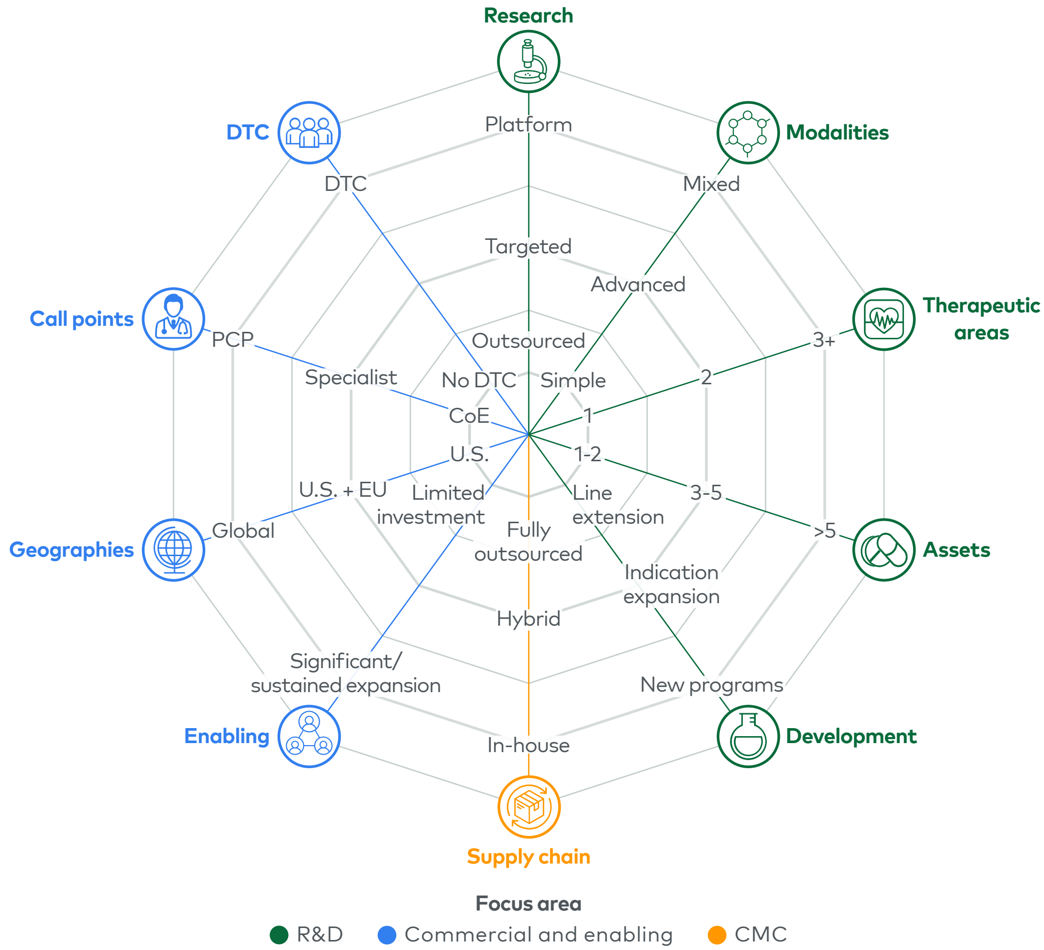
This investment ramp begins well before launch, as organizations conduct late-stage clinical trials, expand chemistry, manufacturing and controls (CMC) capacity, establish commercial infrastructure and build out enabling functions. The spend curve does not flatten after launch: Companies continue to invest heavily in commercialization, life-cycle management and pipeline advancement.

This dramatic escalation in spending underscores the need to strike a careful balance between investing enough to sustain growth and ensure long-term competitiveness while avoiding excessive build-out that erodes economic return. Companies must therefore apply greater discipline in capital allocation and adopt governance structures suited to navigating this trade-off — ensuring that investments are sequenced, right-sized and aligned with a credible path to profitability and shareholder value creation.

Increased decision-making complexity

As a company transitions toward commercialization, its investment universe expands exponentially. Several years before launch, most decisions sit squarely within R&D. But as launch nears, the aperture widens, and funding must now be allocated across research, development, CMC, commercial and enabling functions. The complexity multiplies further as emerging biopharma companies layer in new diseases, modalities, geographies, customer segments and supply chain capabilities while preparing for and beginning launch of their first product (see Figure 2).

Figure 2
Vectors of investment decision complexity

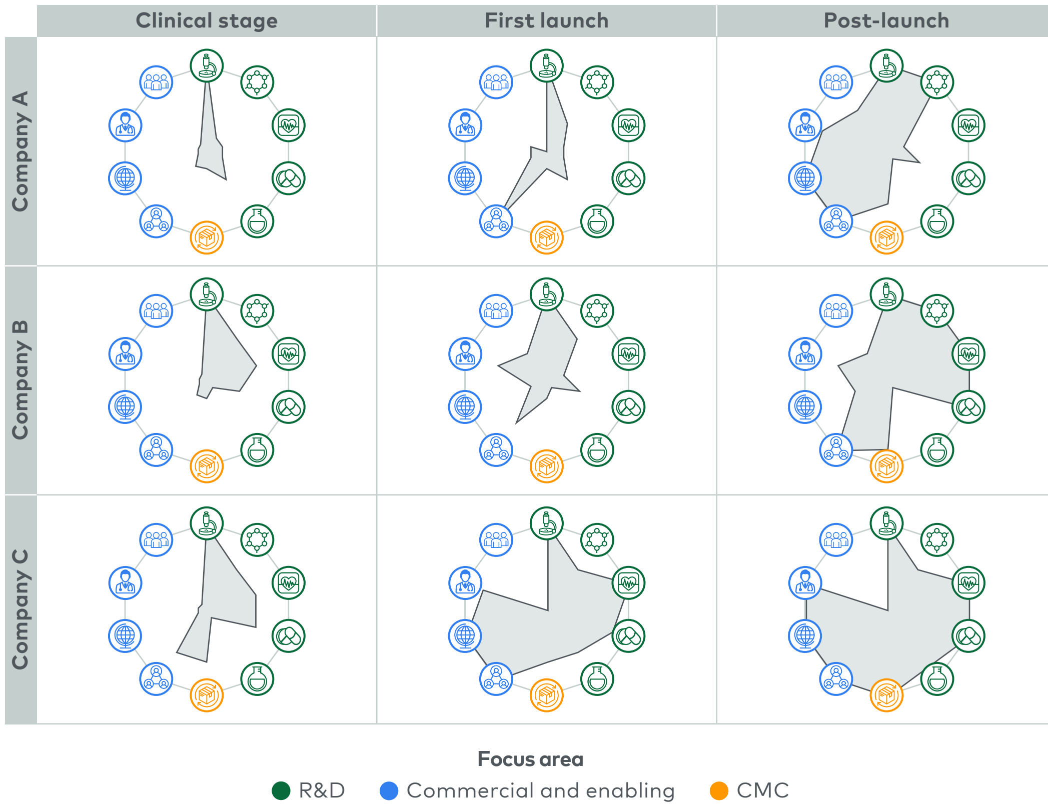


Note: DTC=direct-to-consumer; PCP=primary care physician; CoE=center of excellence; CMC=chemistry, manufacturing and controls
Source: L.E.K. research and analysis

Navigating this growing web of choices demands a fundamental mindset shift from a science-centric focus to an enterprisewide, cross-functional approach to investment — a shift that integrates R&D, commercial, and enabling teams through greater operational and strategic complexity.

Three examples of U.S. rare-disease first launches illustrate how rapidly investment complexity expands in these companies and how different operating models shape distinct decision paths: Company A leaned heavily into commercial expansion, broadening geographies, call points and patient-finding activities. Company B maintained a focused commercial footprint while doubling down on pipeline growth. Company C invested to drive near-term commercial performance and long-term portfolio value. Despite these differences, all faced a sharp rise in the breadth and complexity of trade-offs at and after launch, as reflected by the expanding area in the spider chart (see Figure 3).

Figure 3
Investment decision complexity evolution



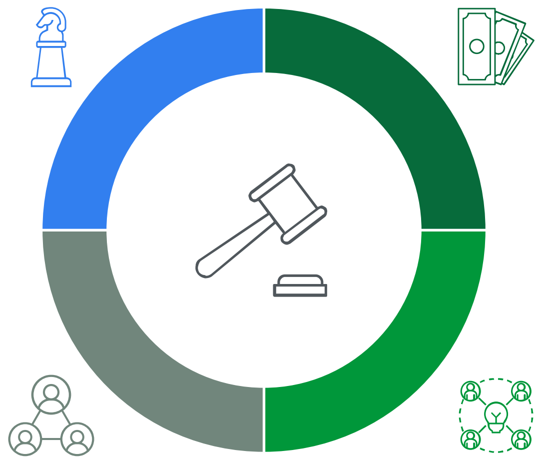
Note: CMC=chemistry, manufacturing and controls
Source: L.E.K. research and analysis

One of the greatest challenges inherent in this increased decision-making complexity lies in managing fundamentally different types of investment decisions, each with distinct evidence bases, payback horizons and strategic implications. Research investments occur a decade or more before revenue materializes and carry high scientific risk, while commercial investments are more de-risked and can deliver immediate topline impact. The strategic intent also diverges: Commercial spend and CMC spend aim to drive near-term revenue and profitability, whereas research and development fuel long-term sustainability. Building the processes and capabilities to rigorously compare and prioritize across these decision types is essential for emerging biopharmas to sustain shareholder value creation beyond first launch.

Transforming the enterprise model to prosper

From our experience working with a broad ecosystem of emerging biopharma companies as they navigate the transition from R&D to the commercial stage, we have identified four actions that materially improve investment rigor, organizational effectiveness and enterprise decision-making (see Figure 4).

Figure 4
Key success factors in transforming to a prosperous enterprise model



Source: L.E.K. research and analysis

1. Decide where to invest

As biotech companies approach their first product launch, they must look beyond near-term execution. Investors quickly shift their focus from launch performance to the company's long-term growth trajectory. Sustaining valuation and evolving the equity story requires a clear strategy for incremental investments that extend value creation beyond the initial launch and establish the foundation for future growth.

Leaders must draw a firm distinction between committed and incremental spending: Committed investments deliver the base plan and maintain essential launch operations. Incremental investments are discretionary and include expansions, accelerations, or upgrades that enhance performance beyond the baseline and create upside value.

A single, transparent inventory of incremental opportunities with defined ownership, objectives, cost, expected value, and timing helps leadership concentrate on meaningful trade-offs and avoid repeated debates about what is "in the base." As initiatives mature and consistently demonstrate value, they can migrate into the baseline.

To ensure comparability across functions, all initiatives should be assessed using a unified framework spanning strategic fit, cost, timing, risk and value (see Figure 5). Metrics such as unmet need (in research), probability of success (in development) and peak revenue (in commercial) should be tailored to reflect different investment archetypes. These scores create a shared fact base to inform, not replace, executive judgment and to enable structured, cross-functional debate. The result is disciplined, enterprisewide investment decisions that support both near-term execution and long-term value creation.

Figure 5

Applicability of criteria to investment archetypes

<table>
<tr><th></th><th colspan="5">Investment trade-off framework</th></tr>
<tr><th></th><th>Strategic fit</th><th>Cost</th><th>Timing</th><th>Risk</th><th>Value</th></tr>
<tr><th>Archetypes</th><th>Ability to deliver strategic objectives</th><th>Scale of up-front and recurring costs</th><th>Time before investment can deliver returns</th><th>Likelihood of investments delivering value</th><th>Expected returns investments can deliver</th></tr>
<tr><td>Research</td><td>Alignment with strategic priorities
Level of innovation</td><td rowspan="5">Near-term cost requirements
Recurring cost requirements
Total cumulative costs</td><td rowspan="4">Time to next key inflection point
Time to revenue generation
Time to breakeven point</td><td>Technical probability of success</td><td>Unmet needs
Portfolio sustainability</td></tr>
<tr><td>Development</td><td>Alignment with strategic priorities
Financial catalyst</td><td>Clinical probability of success</td><td>Peak/cumulative revenue
NPV/valuation</td></tr>
<tr><td>CMC</td><td>IP protection</td><td>Supply chain and manufacturing risk mitigation/resilience</td><td>Capacity/revenue uplift</td></tr>
<tr><td>Commercial</td><td>Alignment with strategic priorities
Financial catalyst</td><td>Commercial execution probability of success</td><td>Peak/cumulative revenue
NPV/valuation</td></tr>
<tr><td>Enabling</td><td>Alignment with strategic priorities</td><td>Time to upgrades/ efficiency gains</td><td>Operational risk mitigation</td><td>Efficiency gains</td></tr>
</table>

Note: CMC=chemistry, manufacturing and controls; IP=intellectual property; NPV=net present value
Source: L.E.K. research and analysis

2. Evolve governance and decision-making

As organizations scale and decision complexity intensifies around a first launch, governance must evolve. Decision rights should be explicit so teams understand who proposes, who challenges and who decides. A standing governance forum aligned with the corporate calendar should oversee enterprise, portfolio and functional investments to ensure timely decisions, coordination, and structured escalation to the executive team or board when needed.

A predictable decision cadence that is anchored to the annual plan, a midyear strategic refresh and portfolio checkpoints tied to major readouts help with management of decisions that run on different timelines. Funding should be linked to objective milestones (e.g., completion of investigational new drugs, trial readouts, launch progress, profitability acceleration). Equally important to continually strengthening the next cycle are post-investment reviews that capture what was funded, what happened and what was learned.

As the organization grows, the mid-layer becomes vulnerable: Roles narrow, responsibilities fragment and connection to senior leadership can erode. Clarifying ownership for each critical investment decision and empowering midlevel leaders as active contributors helps prevent this disconnect. While most companies can enhance investment rigor without altering reporting lines, a targeted structural review is prudent to ensure no barriers impede decision quality and to preserve clear pathways for midlevel leaders to access senior governance bodies and escalate issues when needed.

3. Expand the talent pool while preserving culture

The transition from an entrepreneurial R&D environment to a more specialized commercial organization requires shifting to a different talent profile. The early-stage "generalist athlete" who is comfortable wearing multiple hats and navigating ambiguity becomes less scalable as operational complexity increases. To support launch and growth, companies must recruit specialists with deeper functional expertise, often from larger, more structured organizations.

This diversification of talent can introduce risks. New hires may bring a bias toward process over outcomes, consensus-driven decisions, or a focus on building hierarchical teams rather than enabling speed and agility. The right balance blends the adaptability and ownership orientation of the original biotech culture with the functional depth of experienced leaders from scaled organizations. Achieving this balance requires thoughtful selection, structured onboarding and clear expectations about how decisions are made and how work gets executed in scaling the enterprise.

At the center of successful talent expansion is cultural stewardship. The cultural hallmarks seen across many of our biotech clients, such as confidence in the science, resilience through setbacks, openness to risk-taking, adaptability to shifting competitive and capital conditions, and deep patient focus, must not dilute as the company grows. These traits often empowered the company to achieve its first approval. Codifying the principles that define "how we win," reinforcing them through hiring, development and recognition, and role-modeling them at the top ensure the organizational culture remains a catalyst rather than a casualty of scale. Vertex, for example, grounds its organization in four value principles — commitment to patients, innovation as lifeblood, fearless pursuit of excellence and the primacy of "we" — that guide performance and decision-making across the enterprise.

4. Align the organization around enterprise ambition and strategic priorities

As companies transition from R&D to the commercial stage, execution quality depends on how clearly the organization understands where the company is headed, why it matters and how each function contributes. With growth come specialization and added layers, increasing the risk that teams become siloed or lose connection to the enterprise ambition and goals.

Sustaining alignment requires grounding employees, especially the mid-layer, in the company's long-term ambition, its strategic priorities and the few critical value drivers that shape its success. Before launch, this alignment forms naturally around the shared goal of first approval. Post-launch, as responsibilities diversify and operating complexity rises, the mid-layer becomes the pivotal conduit that keeps the enterprise narrative alive and ensures day-to-day decisions reinforce (rather than dilute) strategic intent.

Investor expectations should serve as a valuable orienting signal, a way to understand the external factors that shape long-term value creation. These expectations provide a clear lens on what matters most for sustainable growth, including revenue trajectory, expense discipline and the pathway to profitability, and midlevel leaders in particular must understand how they intersect with the company's strategy. Leaders' ability to internalize these signals and translate them into enterprise choices helps the organization anticipate executive priorities and supports more consistent, forward-looking decision-making.

Next steps: A brief self-diagnostic

Taken together, these four actions create an enterprise model that scales with spend, complexity and organizational growth. To determine where recalibration will deliver the greatest impact, leadership teams can reflect on the following questions:

- **Investment discipline.** Do we maintain a complete, cross-functional view of both committed and incremental investment opportunities, supported by a unified assessment framework?
- **Comparability and prioritization.** Are investment decisions informed by a consistent set of metrics tailored to investment type, enabling transparent trade-offs across functions?
- **Governance and decision rights.** Are decision rights (i.e., who proposes, who challenges, who decides) explicit, codified and consistently applied across enterprise, portfolio and functional investments? Do we operate against a predictable corporate planning cadence (e.g., annual plan, midyear refresh, milestone-based checkpoints) that keeps decisions moving?
- **Talent and culture.** Have we struck the right balance between early-stage entrepreneurial talent and specialized hires from larger organizations while actively preserving the cultural attributes that drove our initial success?
- **Enterprise alignment and investor expectations.** Do teams across all levels, not just the executive suite, understand the enterprise ambition, strategic roadmap and evolving investor expectations, and how their decisions influence the company's long-term value drivers?
- **Midlevel empowerment.** Are midlevel leaders sufficiently empowered, connected to enterprise strategy and able to escalate insights and risks to senior governance bodies?

For more information, please contact us.

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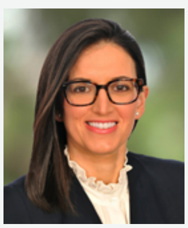

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