

Portfolio Strategy

Addressing New Challenges in Portfolio Decision Making

The pharmaceutical and biotechnology industries continue to face challenges to their historical business models. For the past decade, most companies could plan for success by focusing R&D investment on those molecules offering “blockbuster” potential while orienting sales and marketing efforts toward the treatment decisions made by physicians. It is clear that this is unlikely to be a winning strategy over the course of the next ten years.

What are the keys to success in the future? The answer to this question is less clear, but companies are starting to explore a wide range of strategic options as they face uncertainty over how the industry will evolve in the next decade and beyond. Among the new challenges companies face in portfolio decision making are how to adapt to the rising payer influence on drug utilization and how to navigate the opportunities and risks associated with emerging markets for pharmaceuticals. In our work with diverse clients in the life sciences industry, we have found that an interdisciplinary approach and independent perspective provide clarity around the strategic choices, and associated risks, these companies face in making their most important decisions.

The time is ripe for pharmaceutical and biotechnology companies to reassess their **portfolio strategies**: those decisions that require evaluation of trade-offs across multiple assets, within a particular disease segment or franchise, among one or more therapeutic areas, or, perhaps, across an entire portfolio of molecules in development and in the market.

Strategy development must begin with an understanding of the drivers of change for the biopharmaceutical industry, including: the increasing influence of the payer (both private and public) in determining the therapies patients receive; a heightened scrutiny of the industry's sales and marketing practices; and a dramatically slowing growth rate of sales in developed markets due to generic incursion. In addition, the cost of bringing new therapies to market continues to rise with little or no sign of improvement in development attrition rates.

Even the largest pharmaceutical companies find that they cannot participate effectively in all therapy areas and are consciously choosing where to compete and where to exit. One consequence of this trend for tighter therapy area focus is increasing competition in the fastest-growing segments, such as oncology and arthritis/inflammation. In these areas, willingness to invest is insufficient for success; to win, companies must develop differentiated competitive advantages.

What complexities must be addressed in crafting portfolio strategy? Since multiple molecules are involved, many specific decisions and associated uncertainties must be considered; typically, they are interrelated. Common challenges in strategy development include:

- Appropriate framing of strategic issues
- Robust consideration of alternatives
- Adequate level of rigor in evaluation

APPROPRIATE FRAMING OF STRATEGIC ISSUES

Perhaps the most common challenge in strategy development is that of framing the set of strategic issues that need to be addressed. Here, framing refers to both identifying the scope of issues and the process used to involve decision makers. If the scope is too narrow, key decisions or uncertainties directly relevant to the situation may be missed. For example, in developing a franchise strategy for multiple assets in a therapeutic area, the scope should include both the lifecycle strategy for each asset and potential competitive responses. If either is ignored, the resulting strategy will not be robust and will likely need to be revisited within the course of a year, due either to product strategy decisions that arise or to a changing competitive landscape.

As the payer becomes an increasingly powerful stakeholder in nearly every geographic market, so grows the importance of a strong economic value proposition for any new therapy. The challenge to strategy development is to effectively incorporate payer concerns into the scope of portfolio decision making without losing sight of the relevant nuances of the therapeutic landscape. Many companies are incorporating health economics and outcomes research in earlier stages of product development, and some are establishing entirely separate functions to focus on the market access issues of pipeline products.

■ CASE IN POINT

A global pharmaceutical company faced challenges to continued growth across a portfolio of therapeutic areas (TAs) ranging from mature to emerging. Analysis Group conducted a comprehensive assessment of the company's investment strategy by providing perspective on portfolio prospects through multiple "lenses." To highlight the extent to which the client's existing portfolio addressed high-growth therapeutic opportunities, one lens compared the company's TA footprint against industry-level growth rates and values (Figure 1a). Another lens characterized the extent to which R&D investment was being deployed in the most productive TAs (Figure 1b). Insights drawn from these and other perspectives led to consideration of alternative portfolio profiles. As a result, the client shifted from a mixed primary care/specialty pharmaceutical model to a portfolio focused on high-growth specialty segments.

Using Multiple Lenses to Assess Growth Prospects

Figure 1a. Expected Value by TA Size and Growth Rate
(Each circle aggregates the programs within a therapeutic area)

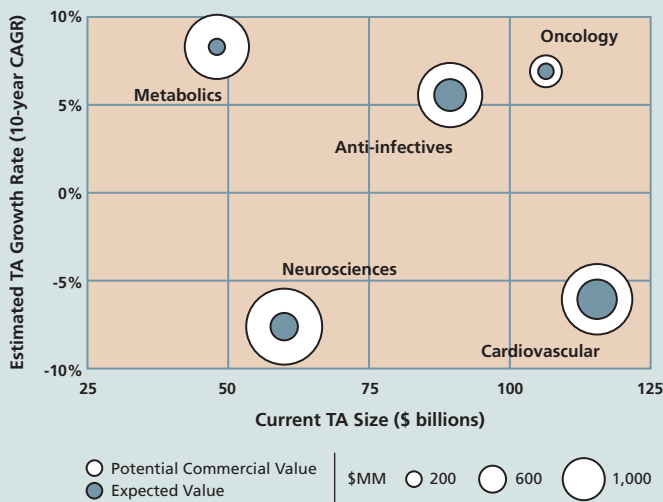
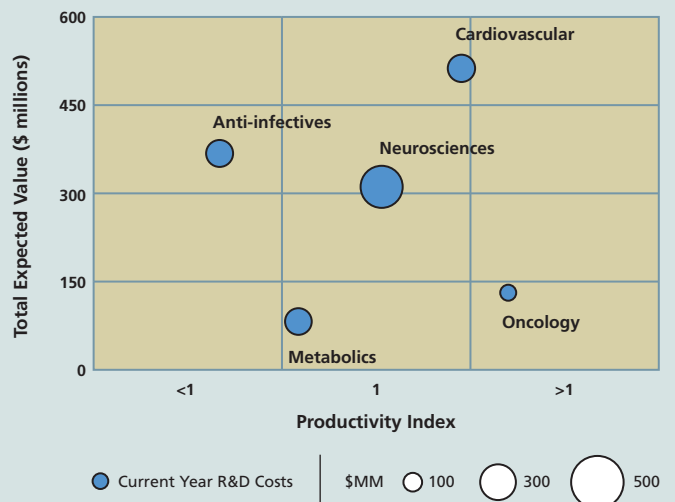


Figure 1b. R&D Investment by Productivity and Expected Value
(Each circle aggregates the programs within a therapeutic area)



If the scope is too broad, the strategic issues under consideration become harder to manage. Without criteria to determine what information is relevant, a strategy development effort could become a lengthy market assessment exercise. This could occur when developing strategies in complex therapy areas such as immunology or oncology, in which many therapeutic classes show promise across multiple disease segments. In segments such as hepatitis or hepatocellular carcinoma, emerging pharmaceutical markets – for example, China, India, and Brazil – cannot be ignored. Strategy teams may resort to broad assessment frameworks that appear to span the scope of interest, but too often these provide few new, actionable insights. Decision makers are presented with detailed information on the market, but with little guidance on how to create a strategic position that fits with their company's objectives.

Rigorous analytical approaches are required to ensure proper framing of the strategic challenges to be addressed. One such approach starts with identifying and then categorizing decisions that may be relevant to the strategy. The next step is to focus on the subset of related decisions that should be made promptly. This both guides information gathering and helps to identify which internal stakeholders need to be involved in the strategy process. Long-term portfolio strategy requires cross-functional engagement – spanning discovery, development, marketing, manufacturing, commercial operations, and business development – both to include these perspectives in decision making and to align the organization for implementation.

ROBUST CONSIDERATION OF ALTERNATIVES

A strategy is a deliberate choice of actions and investments to create value. Strategies offering competitive advantages require trade-offs in terms of resources, risk, time, and anticipated value. Discussion of strategic alternatives is central to the strategy development process but, surprisingly, such alternatives are often not explicitly articulated at all. If decision makers are presented only with recommendations and little or no analysis of the alternatives and associated trade-offs, a key step will be missed in the process.

Novel development strategies should be given full consideration in the pursuit of a portfolio of products offering competitively superior differentiation. For example, to significantly improve the cost/benefit profile of a drug, and the attainable price and level of access, it may be worthwhile to target those patients with the greatest unmet need, as opposed to pursuing the broadest potential patient population. While a stratified patient approach based upon clinical response is quite common, increasingly, companies are examining the economic implications of these approaches, as well.

We typically expect three to five distinct, compelling strategic alternatives to be considered. These alternatives should be identified early in the strategy process to ensure efficient, effective consideration.

■ CASE IN POINT

The most profitable franchise of a leading pharmaceutical company held a maturing portfolio, with its flagship product facing loss of exclusivity. Senior management had to decide whether to exit the therapy area or to significantly reinvest. A strategic assessment of the market, which included potential opportunities in developing countries, confirmed the long-term attractiveness of the therapy area and provided the rationale for investment. We supported the franchise leadership in defining and evaluating their strategic alternatives. The scope of decisions spanned investments in discovery, development, and global commercial infrastructure, as well as in partnerships and acquisitions. The long-term recommendations guided more than \$1 billion of investment and resulted in an increase of more than \$10 billion in shareholder value.

Sometimes, companies fail to investigate innovative strategic alternatives when teams are constrained by motivational biases. This is especially of concern when externally focused opportunities, such as acquisitions or partnering, are involved. When optimizing allocation of R&D resources across a portfolio of development assets, a product team may evaluate multiple resourcing alternatives, but may not consider the potential benefit of out-licensing or partnering. Some internal assets may be of significantly greater value to another company than to the originator – and that potential value will be lost if licensing or partnering alternatives are not considered.

The process used to develop portfolio strategy must explicitly require early generation of alternatives to ensure strategic options are efficiently and effectively considered. Otherwise, key stakeholders may raise new alternatives late in the process, when the team should be focused upon the recommendations and implementation plan. The result: additional iteration on evaluation or dismissal of the new alternative and whatever insights it may offer. Loss of efficiency is the best case consequence of neglecting alternatives; more troubling, the result could be a surprise move by a competitor – for example a game-changing acquisition – that should have been considered during strategy development.

ADEQUATE RIGOR IN EVALUATION

A third challenge in effective strategy development is evaluating the implications of the strategic alternatives with an adequate level of analytical rigor. Confronted by interrelated decisions and uncertainties, companies often err in the direction of oversimplification. Consider, for example, the critical issue of competitive response, frequently a concern when crafting the franchise strategy for a portfolio of marketed assets. The potential responses of competitors and payers to changes in the positioning, promotion, and pricing/reimbursement elements of a strategy need to be rigorously evaluated. Otherwise, the resulting strategy will not be

robust enough to withstand those changes. A typical consequence of inadequate rigor is that the analysis does not hold up to scrutiny from the full leadership team, resulting in inefficient additional iteration on strategy development and evaluation.

A rigorous approach to strategy development will also incorporate the uncertainties in market access as well as the evolution of emerging markets. It is no longer sufficient to assess market share and price primarily on the basis of the anticipated efficacy, safety, and dosing claims in the product profile. In highly competitive markets, such as those for diabetes or sleep disorders, market access may not follow from regulatory approval. The evaluation must test how well the development plan can deliver the comparative effectiveness research and value-oriented endpoints important to government authorities and private payers.

Similarly, the geographic distribution of value for pharmaceutical products is becoming more fragmented, requiring more refined distinctions than in the past. Success in emerging markets typically requires a detailed understanding of the

■ CASE IN POINT

Analysis Group helped a major pharmaceutical company assess the implications of the evolving U.S. health care landscape on its pipeline and in-market portfolio. Specific issues of concern focused on payer decision making: the application of comparative effectiveness research, and increased payer emphasis on evidence-based medicine (Figure 2). We helped develop macro-level environmental scenarios and used them to identify those products most sensitive to changes in the future payer environment. This analysis was used to guide the development of focused investment options to mitigate downside risks and enhance the likelihood of improved competitive positioning.

Figure 2. Assessing the Portfolio Implications of Changes in the U.S. Payer Environment

U.S. Payer Value Scenarios

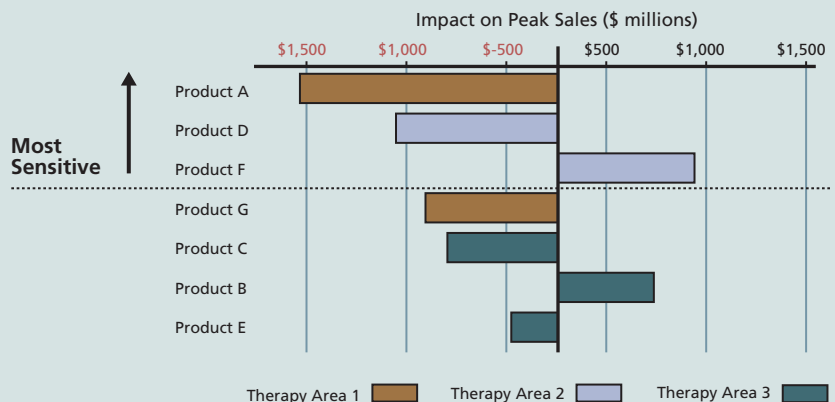
“Aggressive”

- CMS adoption in 2013
- EBM impact ceiling 30% of share
- Full data impact of CER in 2014 for high priority TAs, 2017 for lower priority TAs

“Moderate” (Base Case)

- No CMS adoption until 2017
- EBM impact ceiling 10% of share
- Full data impact of CER in 2015 for high priority TAs, 2019 for lower priority TAs

Portfolio Sensitivity to Aggressive Payer Value Scenario



regulatory and competitive environment at both the country and disease levels. In markets such as China, uncertainty surrounding the future commercial opportunity may be as significant as clinical and regulatory risks. Companies using a portfolio-level segmentation defined by North America, the five largest European countries, Japan, and “rest of world” will find themselves at a disadvantage in the fastest-growing markets.

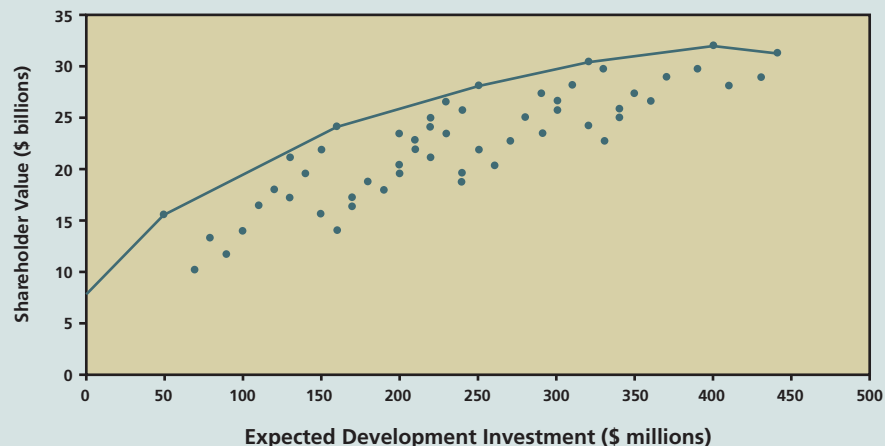
One approach to determining the appropriate level of detail is to return to the set of decisions and associated choices, and then focus on the metrics to be used in identifying the best overall strategy. Companies need appropriate distinctions pertaining to investments, risks, and potential value to understand the implications of different choices, and assessments should characterize both what is known and what is unknown. For easily defined uncertainties, such as the likelihood a development asset will achieve specific clinical endpoints, the language of probability works well. To consider more complex uncertainties such as competitive response, the degree of rigor necessary may range from scenario analysis to competitive role-play simulation, or “wargaming.”

■ CASE IN POINT

The portfolio of a leading biotechnology company had grown in both breadth and complexity. The company sought a disciplined approach to evaluate the potential value of development programs, inform lifecycle management strategy, and support portfolio optimization. Working with a senior cross-functional team, we designed a decision process with a supporting evaluation methodology tailored to the client’s needs by leveraging both internal and external best practices. This process helped management identify the set of funding decisions that maximized the value of the portfolio under resource constraints (Figure 3). The client successfully piloted the process during its annual planning, and created an internal team to manage the process and support ongoing portfolio decision making.

Figure 3. Developing a Process for Evaluating Portfolio Value

Each point represents an alternative set of portfolio funding decisions. A point on the upper boundary represents an “efficient” portfolio – one that maximizes shareholder value conditional on investment.



ELEMENTS OF A DISCIPLINED APPROACH TO PORTFOLIO STRATEGY DEVELOPMENT

The specific details of the portfolio strategy development process will always depend on the context and culture in which the strategy is imbedded, but several elements are critical to a disciplined approach:

- ***Conscious consideration of the scope, process, and people to involve***
Begin with a clear definition of the scope of decisions, and assessment of the key uncertainties that must be understood to develop a robust strategy. Involve in the strategy development process the people who will be responsible for executing the strategy.
- ***Focus on the key decisions that must be made***
For decisions in scope, systematically explore the range of choices. Challenge the strategic thinking by considering what strategies competitors might pursue and test alternatives against external scenarios to ensure robustness.
- ***Tailor the evaluation approach to the problem, not the other way around***
Center the strategic analysis on the decision criteria and add complexity only where additional insight is needed.

For more information on Analysis Group's portfolio strategy services, visit www.analysisgroup.com or contact Vice President William Leaf-Herrmann (617 425 8166; wleaf-herrmann@analysisgroup.com) or Managing Principal Edward Tuttle (650 463 2702; etuttle@analysisgroup.com).