

Managing innovation strategy

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Innovation Strategy as a Top Management Priority

R&D has long been perceived as the holy grail of the pharmaceuticals, diagnostics, and medical devices industries, and rightly so. While improvements in processes such as distribution and customer service can create incremental value for companies, it is the “quantum leap” innovations in products and technologies that yield the huge growth and profitability improvements demanded by shareholders. And while many factors are necessary for success, the companies who best manage their innovation process tend to enjoy differential returns: Pfizer, who has invested heavily in innovation and is renowned to have one of the strongest R&D pipelines in the industry, outperformed the Dow Jones pharmaceuticals index by 48% over the period 1991 to 1997, even before the introduction of Viagra.

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But the hurdle is rising for companies seeking to develop new products. Despite the adoption of new techniques like combinatorial chemistry and high through-put screening that have greatly improved the productivity of drug discovery, the average R&D investment required to bring a new drug to market

has more than doubled in the past decade, rising from \$230MM to \$500MM or more. In the medical devices industry, the cost to develop just one product can exceed \$100MM. Furthermore, R&D investments are still extremely risky, with only 2-7% of all pharmaceutical innovation projects ever making it to market.

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A number of factors are to blame for these spiraling innovation costs. First, the “low hanging fruit” of the health care industry has in many cases been harvested. Advances in treatment and technology have brought under control many of the better understood diseases and conditions, and companies are now focusing on indications that are increasingly complex, some of them targeting even narrower patient populations.

Second, pharmaceutical companies now face even more stringent regulatory requirements for clinical studies and approval of drugs applying novel technologies.

Third, the rise of managed care approaches, combined with the availability of more products for the same indication, has led to heightened emphasis on the economics of new drugs and products, especially in the United States. Regulators and payers alike now assess not only a product’s performance, but its impact on overall system costs. Often, significant total therapy cost improvements are required for the product to gain market acceptance, thus creating increased challenges for the R&D organization. This trend is likely to intensify in coming years as managed care gains favor around the globe.

In the midst of these fundamental changes, however, a few companies manage to wring exceptional returns from their innovation dollars, and produce “blockbuster” drugs and products that lead them to market dominance. What distinguishes these companies?

Our experience working with the leaders in the global health care industry has convinced us that being a world-class innovator requires not just great scientists and research facilities. It requires a great *process* for managing the generation, development, and in some cases, acquisition of ideas. This process must provide a systematic method for evaluating, prioritizing, and investing in the best research projects, and then driving these projects through the development stage to generate profitable products. Critical to the success of this innovation process is a direct link to the corporate and/or business unit strategy of the company¹.

Innovation as Strategy: The Importance of Process

Corporate strategy, innovation strategy, and R&D need to be explicitly connected, and in the best-run organizations they are indeed tightly linked. The enormous sums invested in R&D, the lengthy time-to-market for pharmaceutical, medical devices and diagnostics products, and the high risk of development failure make it critical that innovation strategy, resource allocation, and ultimately, the activities of the R&D department are carried out with the broader corporate strategy in mind.

To illustrate, consider some of the questions managers face as they fashion an effective innovation strategy:

- What are the key medical and pharmacoeconomic challenges of the future?
- In which therapeutic areas does the company hold the greatest pockets of knowledge, competence, and resources, and how can they be leveraged?
- Which clinical indications/physiological pathways and market segments should the company target?
- How do customers define therapeutic/medical value, and what are the key levers and associated profit economics by which we can create a compelling value proposition for them²?
- What data should the company generate during development to prove the value proposition?
- What revenue and profit targets need to be achieved?
- What resources are available for reinvestment?

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A sound strategy, devised at the highest levels of the organization, will take all of these factors into consideration. Yet the activities that turn strategy into results occur further down in the organization, and when the link between corporate strategy and innovation strategy breaks down, the results are predictable: R&D teams drift into projects that aren't leveraged, while exceptional capabilities within the organization are under-utilized; products are generated that offer no advantages relative to those of competitors, or worse, aren't viewed by customers as providing significant value; key decision-makers lack a clear definition of desirable outcomes, and so misallocate scarce resources.

When the link is clearly established, however, the results can be dramatic: an R&D organization leveraging its core competencies to bring to market products that

- 1] represent fundamental pharmacoeconomic or medical improvements over existing offerings,
- 2] are valued by key customer groups, and
- 3] improve the overall strategic positioning of the company.

When all these gears are turning together, the result is higher profits and higher share prices. Profits can then be funneled back into innovation, perpetuating a “virtuous cycle” of value creation.

What follows is a framework for systematically managing the assessment, prioritization, and development of research projects. While it is understood that the innovation process must remain linked to a company's overall strategy, this paper focuses only on managing the innovation process, and does not directly discuss the steps needed to develop a long-term corporate strategy.

Managing the Innovation Process

The goal of the innovation framework presented here is to create a structured approach to the innovation process, ensuring that the most promising research projects are invested in and eventually brought to market, and that the innovation strategy is carried out in concert with the broader corporate strategy.

To illustrate, let's use a hypothetical example. Assume that a pharmaceutical company — we'll call it PharmCo — has decided after a strategic review to bolster their presence in cardiology. To do this they are seeking to develop drugs to combat a variety of indications, including, for the sake of argument, hypertension. Working together in an iterative process, the marketing, sales, and R&D departments have established a set of revenue and profit targets and timelines. Now the organization must deliver.

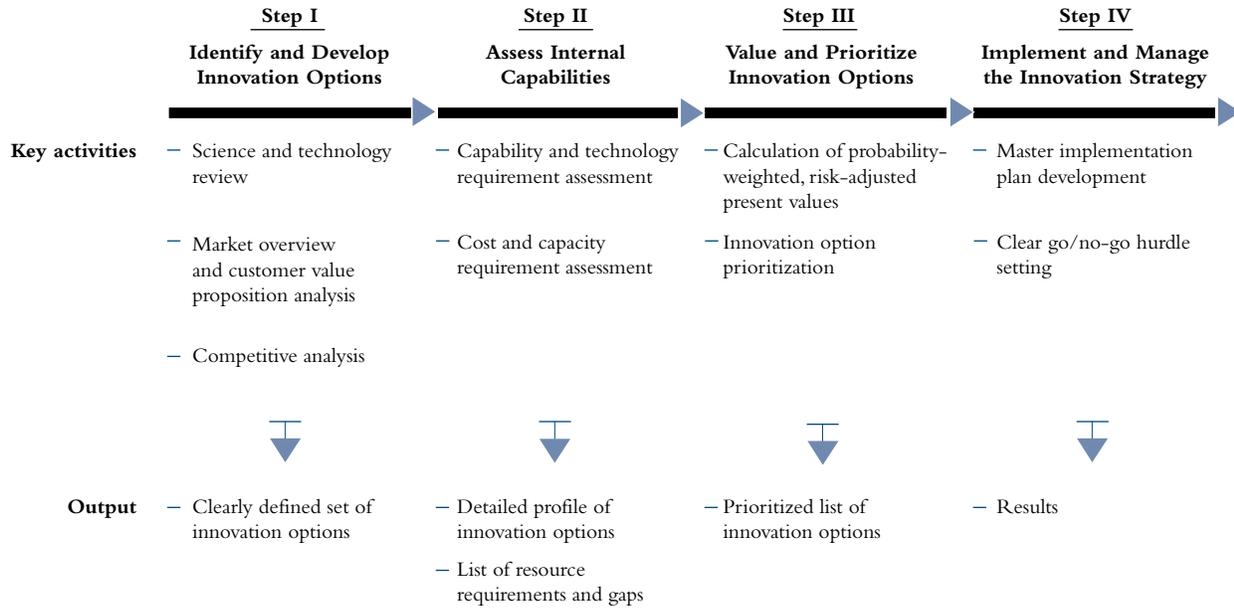
Based on an understanding of the underlying pathology and the regulation of blood pressure, scientists have identified “biological mechanisms” to regulate either cardiac output or peripheral vascular resistance. For decades, drugs such as diuretics or β -Adrenergic antagonists (commonly known as β -Blockers) have been on the market to treat hypertension. Other drugs such as Renin inhibitors that target different sites or work via alternative pharmacological mechanisms are still in clinical development.

Questions surround these different mechanisms: Which will provide the most efficacious treatment for hypertension? What will be the pharmacoeconomic impact of each possible drug? And will any of them fulfill the strategic objectives — such as revenue and profit targets and competitive positioning — that have been laid out for the company?

¹For the sake of simplicity, the term “corporate strategy” will be used throughout this piece to denote either a corporate or business unit strategy.

²A value proposition is defined as the combination of attributes of a product or service that a specific customer segment values differentially versus competitors' products. For some customers, a product's value proposition may be driven primarily by one attribute, such as price, or quality. Other customers may consider a combination of attributes, such as price, quality, and convenience, in evaluating a product's value proposition.

Figure 1: Innovation Framework



In the midst of these unknowns, PharmCo must decide upon an innovation strategy. The framework that allows us to prioritize the allocation of our innovation investments is as follows (**Figure 1**):

Step I: Identify and develop innovation options

Step II: Assess internal capabilities

Step III: Value and prioritize innovation options

Step IV: Implement and manage the innovation strategy

This is a straight-forward approach. Its power derives not from any new analytic tool or valuation technique, but from its insistence that the decision-maker consider innovation investment systematically, in a way that coordinates with the overall strategic direction of the company.

Step I: Identify and Develop Innovation Options

A pharmaceutical “innovation option” is a possible investment in one or a set of treatment mechanisms that together represent a distinct strategy for developing a product to treat a stated indication. In medical devices and diagnostics, an innovation option consists of one or a combination of product prototypes or technologies. To better illustrate both what constitutes an innovation option and to demonstrate how these options fit into the broader context of our framework, let’s continue with our PharmCo example.

As mentioned before, a strategic review has established cardiology, and in particular hypertension, as key areas of focus for PharmCo. Revenue and earnings growth targets have been set, and a budget has been allocated for the generation and development of new products. But there are numerous mechanisms for developing a drug to treat hypertension. Which are viable, and how should PharmCo allocate their scarce R&D resources?

We begin by assembling a robust fact-base consisting of three primary elements:

- 1) a science and technology review,
- 2) a market overview and customer value proposition analysis, and
- 3) a competitive analysis.

Once we have assembled our fact base we can develop the different innovation options available to us.

I.1 Science and Technology Review

By surveying our internal scientific knowledge-base and R&D department, talking to outside experts (academics, independent scientists, even competitors), reviewing contemporary literature, and utilizing emerging sources of information (such as Genome projects), we can develop an understanding of all the known mechanisms for fighting hypertension. We must also investigate any drugs that are either on the market or in development, seeking to understand their pharmacological mode of action, stage of development, likelihood of development success, projected time to market, patent status, and availability for licensing. Technologies for generating and screening molecular leads should also be investigated, with the goal of identifying the technology owner, patent status, and availability for licensing if the technology is not available in house.

Output: A list and basic understanding of all possible mechanisms that are available to us for fighting hypertension. A list of technologies that could assist in the identification, testing, and production of different possible molecules (drug candidates).

To create a “breakthrough” product, there must be a fundamental improvement over the existing value proposition.

I.2 Market Overview and Customer Value Proposition Analysis

We have two goals as we conduct the market and customer overview: to refine our estimates of the potential revenues and profits available to us from each of the mechanisms under research, and to clearly identify the key levers necessary to create a superior value proposition for hypertension treatment.

First, we already have an idea from our prior strategic review of the broad demographics and market potential of a new hypertension drug. But the market potential of a drug could differ based on the mechanism from which it derives. For instance, there may be segments of the hypertension population for which a drug based on Renin Inhibition wouldn't be appropriate due to possible drug-drug interactions or dose-limiting side-effects. If this is the case, the potential market size for Renin inhibitors would differ from that of hypertension products utilizing other treatment mechanisms.

Secondly, we must identify the key criteria that will allow us to develop a product with a value proposition superior to anything currently offered or under development by competitors. In order to create a “breakthrough” product, there must be a fundamental improvement over the existing value proposition (e.g., in improved pharmacoeconomics or via causal rather than symptomatic treatment). The degree of the improvement over current offerings will drive the speed and size of market adoption.

For instance, before Viagra, sufferers of impotence had effective but physically uncomfortable therapeutic options available to them. Viagra is efficacious, but more importantly, it represents a huge quality-of-life improvement over existing therapies. The result has been an extremely fast adoption rate, and a blockbuster product for Pfizer.

The key value proposition criteria as judged by customers will, of course, differ based on the indication being treated, the therapeutic alternatives available to physicians/patients, and the offerings of competitors. Customer groups must be segmented to identify the value they would place on improvements along each of the five criteria for evaluating pharmaceutical products: drug safety, drug efficacy, outcomes, cost effectiveness, and patient quality of life. Once the key customer levers have been identified, each drug candidate should be re-visited to see which might offer improvement on the most important of these key criteria.

The key value proposition criteria will also differ based on who the customer or decision-maker is. For instance, in pharmaceuticals the key decision maker might be the physician actually prescribing the drugs, or it could be a pharmaceutical buyer for a managed care organization. Their selection criteria would likely differ. In the case of medical devices and diagnostics, the key decision-maker could be a scientist, physician, or lab technician, each of whom might also have different selection criteria.

Output: For each treatment mechanism, a detailed customer segmentation highlighting key selection criteria and purchase patterns of the decision maker, penetration and sales curve estimates (taking into consideration the current and future products of competitors), and an estimate of the drug's revenue and "profit pool"³ potential.

1.3 Competitive Analysis

Competitors may be — and probably are — working on projects similar to ours. Their current and future product offerings and strategic intentions will impact how we position our product. For instance, in the case of hypertension, there are a number of effective molecules on the market that exhibit the same mode of action and similar pharmacological responses. This may accentuate the imperative of finding a drug that combats hypertension via another mechanism, or that uses an



The profit pool is the sum of all profits earned along the value chain of an industry, and can be segmented by product, customer group, channel, geography, or other criteria.

existing mechanism but exhibits distinct pharmacological advantages. Alternately, it may simply place more importance on the marketing and sales organizations to effectively sell our product if it is similar to those currently offered.

Identifying trade-offs like these requires a thorough investigation not only of competitors' current and future product portfolios, but of their overall strategic positioning, including relative market share, sales and marketing capabilities, and relative science capabilities. It is important not to underestimate this last point: smaller competitors who have invested differentially in a specific treatment mechanism may hold a significant advantage in product development for that mechanism over larger competitors who have spread their innovation investments across many mechanisms or scientific areas (assuming comparable quality of scientists and availability of technologies). This is so because although a strong element of serendipity still exists in the innovation process, innovation is *not* akin to gambling; indeed, over time, differential investment in certain capabilities will yield differential results.

Output: A profile of key competitors, describing their respective share of the market (revenue and profit pools), key strengths and weaknesses, stated strategy, and a thorough listing of relevant products (current and developmental, including developmental stage, development risk and likelihood of reaching the market, patent protection, licensing status, and availability for licensing).

By combining the three building blocks of *Step I* — science, market, and competition — we are now able to develop a set of innovation options. In our PharmCo example, one innovation option might be to fund research only on Renin inhibition — a fairly risky strategy since there is no guarantee of finding an effective Renin inhibitor drug. A more moderate innovation option would be to invest heavily in research on Renin inhibitors, but to also invest in finding a more pharmaco-economically advanced drug that relies on a mechanism that is already proven (such as Angiotensin II Antagonists) (*Figure 2*). This would allow PharmCo to maintain a presence in the hypertension market should Renin inhibitors not bear fruit.

Clearly a whole array of innovation options can be identified for any given indication and for each strategic scenario. As we develop our options, we must remember the main tenets of the innovation framework. First, we are searching for innovation options that will yield breakthrough products and improved value propositions

rather than incremental improvements⁴. Secondly, each innovation option should represent a distinct strategy for innovating towards a new product, even if some of the elements are shared across options. And thirdly, innovation options need to be consistent with the strategic objectives laid out for the company.

Once we have defined the appropriate innovation options, we then need to more thoroughly assess them in light of our internal capabilities and resources.

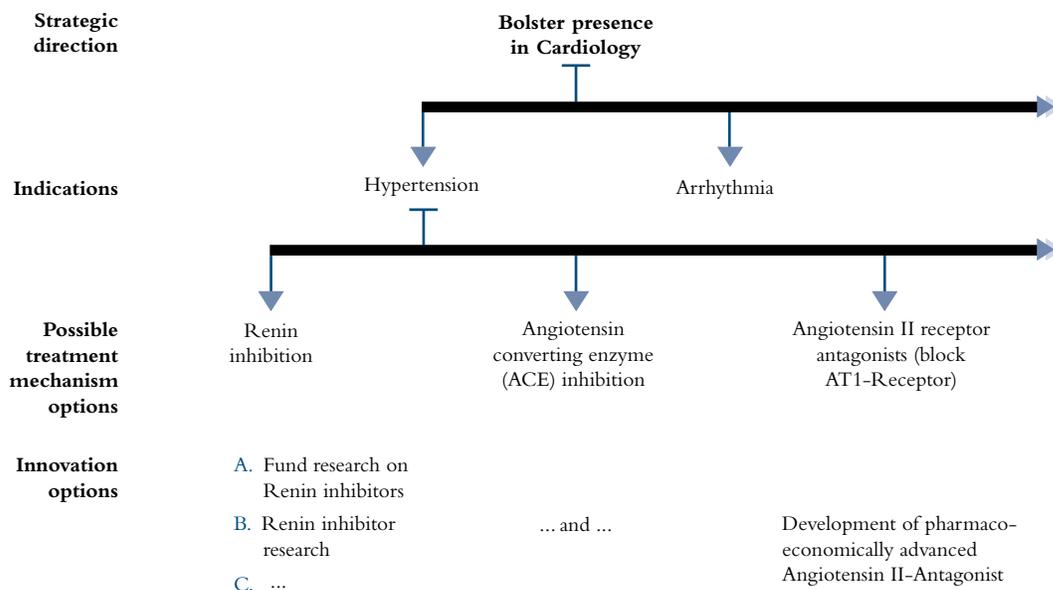
Step II: Assess Internal Capabilities

The focus of *Step I* is primarily external: How big is the potential market? What are competitors up to? What is the state-of-the-art science for each indication? In *Step II* we turn our lens inward in order to better understand the requirements for pursuing each innovation option.

Two primary building blocks make up *Step II*:

- 1] capability and technology requirements, and
- 2] cost and capacity requirements.

Figure 2: Innovation Options of PharmCo



³For more information about profit pools and profit pool-based strategy, please see *Profit Pools: A Fresh Look at Strategy*, Harvard Business Review, June/July 1998 by Orit Gadiesh and James L. Gilbert.

⁴It should be noted that companies can and do create significant value through incremental enhancement of existing products. However, the process for developing these enhancements is different than for developing breakthrough products, and is not covered in this paper.

II.1 Capability and Technology Requirements

The science and technology review of *Step I* provided us with a broad overview of the different innovation options: the “30,000 foot view” of different mechanisms and technologies for pharmaceuticals, and of different technologies and product prototypes for medical devices and diagnostics. Now we must better understand the science of each mechanism, technology, or prototype contained in our innovation options, and identify the resources necessary to develop them⁵. To illustrate, let’s continue with the PharmCo example.

Having outlined our innovation options for a hypertension drug, we investigate each further: What is the actual science behind each treatment mechanism contained in our innovation options? What are the chances of each mechanism’s success or failure, both scientifically and commercially? What would be the likely side-effects or short-comings of a new product? What interactions could be expected with other medications?

Next, we must define the requirements to successfully pursue each innovation option: What are the capabilities, technologies, and expertise required to develop each treatment mechanism? Do these capabilities and technologies exist in-house? If not, can they be developed in-house or must they be sourced via acquisition, alliance, or licensing agreement? What would be the costs of doing so? What are appropriate target companies for this sourcing?

To answer these questions, we begin by cataloguing, for each mechanism, all relevant in-house capabilities and technologies. These may be in the form of current R&D projects, technologies from other projects that could be applied to a new mechanism, existing molecules from past research, or researchers with experience in a given area (**Figure 3**). We then look beyond PharmCo’s walls to identify external innovations and technologies, consulting scientific literature, independent scientists, symposia, and the like.

Figure 3: Capability and Technology Assessment PharmCo

Physiological pathway	Possible treatment mechanisms (pharmacological mode of action)	Drug Discovery		Preclinical Development		Drug Delivery		Manufacturing		Clinical Development													
		Rational drug design	Combinatorial chemistry	Peptide synthesis	...	Disease state models	Toxicology models	Bioanalytics	...	Controlled release formulation	Gene delivery	...	Chemical	Biotechnology	Intermediates	Special dosage forms	...	Novel surrogate markers	Novel endpoints	Active comparators	...		
Renin-Angiotensin-System ↓ Angiotensinogen ↓ Angiotensin I ↓ Angiotensin II ↓ Angiotensin receptor (AT ₁ -R)	Mutant angiotensinogen gene therapy																						
	Antisense strategy																						
	Renin inhibition																						
	Angiotensin converting enzyme (ACE) inhibition																						
	Angiotensin II receptor antagonists																						

Note: Other drugs for treatment of hypertension include diuretics (impact on extra cellular fluid volume and cardiac output) or β-adrenergic receptor antagonist (reducing anterior resistance and venous capacity) and apply different pharmacological mechanisms.

Output: A map for each innovation option of all required capabilities and technologies, and an understanding of the resources and time needed to develop or acquire those we do not have.

II.2 Cost and Capacity Requirements

This is a critical, and often overlooked, element of managing the innovation process. Too frequently, R&D projects are conscripted on a one-on-one basis, only to find that the cumulative requirements of all the various outstanding projects overwhelm the research and development functions. The result is a capacity bottleneck that can cause severe delays in the innovation process, and ultimately, in the development and production of key products.

To avoid these bottlenecks, we must manage not just individual R&D projects, but the entire R&D portfolio. We begin by mapping out the financial and human resource needs for each innovation option. These “resource maps” must then be integrated to give a comprehensive picture of the demands that would be placed on research, development, and production teams over time depending on which innovation options are selected. (Remember that the innovation process we have outlined for hypertension is also being pursued for other indications, and that the organization will need to invest in multiple projects simultaneously.) In some cases, qualified external resources such as Clinical Research Organizations (CROs) can be employed for additional capacity. Any capacity planning should also take into account the likely attrition of projects over time.

Output: Resource maps showing for each innovation option the resource requirements and resulting gaps. Cost estimates and timelines for the development of each innovation option.

Step III: Value and Prioritize Innovation Options

By the time we have completed *Step II*, we have a clear set of innovation options from which to choose. We have also compiled a fact base about the key strategic and tactical elements of each option. The goal of *Step III* is to prioritize our investment in innovation options, using both quantitative and qualitative tools.

We begin by calculating a present value for each innovation option, providing us with an “apples-to-apples” metric for comparing our options. We then balance this quantitative evaluation with a more qualitative strategic perspective, allowing us to direct our allocation of research funds.

III.1 Probability-weighted, risk-adjusted present values

The first step in calculating a present value for each innovation option is to develop a base case financial scenario. In our PharmCo example, we describe the most realistic revenue forecasts of the drug or drugs that would be the output of each innovation option. We then factor in research and development costs (including any additional expenses incurred by acquiring new technologies or adding R&D or production capacity), production costs, sales and marketing costs, overhead, and so on, to arrive at a set of base-case discounted cash flows and a discounted present value.

Things may go better or worse than planned, of course, and we need our valuation to reflect this uncertainty. We incorporate this risk by creating a set of scenarios — at the simplest level, an optimistic and pessimistic scenario — that take into consideration the inherent risks of the business. Typically these risks come in the form of clinical or regulatory failure, market adoption, project attrition or delay, patent issues, or competitive substitution. When combined in a thoughtful and consistent way, the result is three scenarios with different — sometimes very different — cash flows and present values⁶.

⁵In some cases, the same mechanism or technology will feature in more than one innovation option, allowing information to be shared across innovation options.

⁶Alternative methods of valuation, such as option theory, may also be applied to innovation strategy. It is our experience, however, that while option theory may yield more precise valuations, the advanced technical requirements of such analysis render it less pragmatic than present value scenario modeling.

To complete our risk-adjusted present value we must weight each scenario for its likelihood of occurrence. For instance, the optimistic scenario may yield an extremely high present value, but we may give it just a 20% chance of occurring. By combining the optimistic, base case, and pessimistic scenarios with their probability weightings, and then summing them, we arrive at a probability-weighted, risk-adjusted present value for each innovation option (Figure 4). This present value is a consistent metric by which to compare different innovation options.

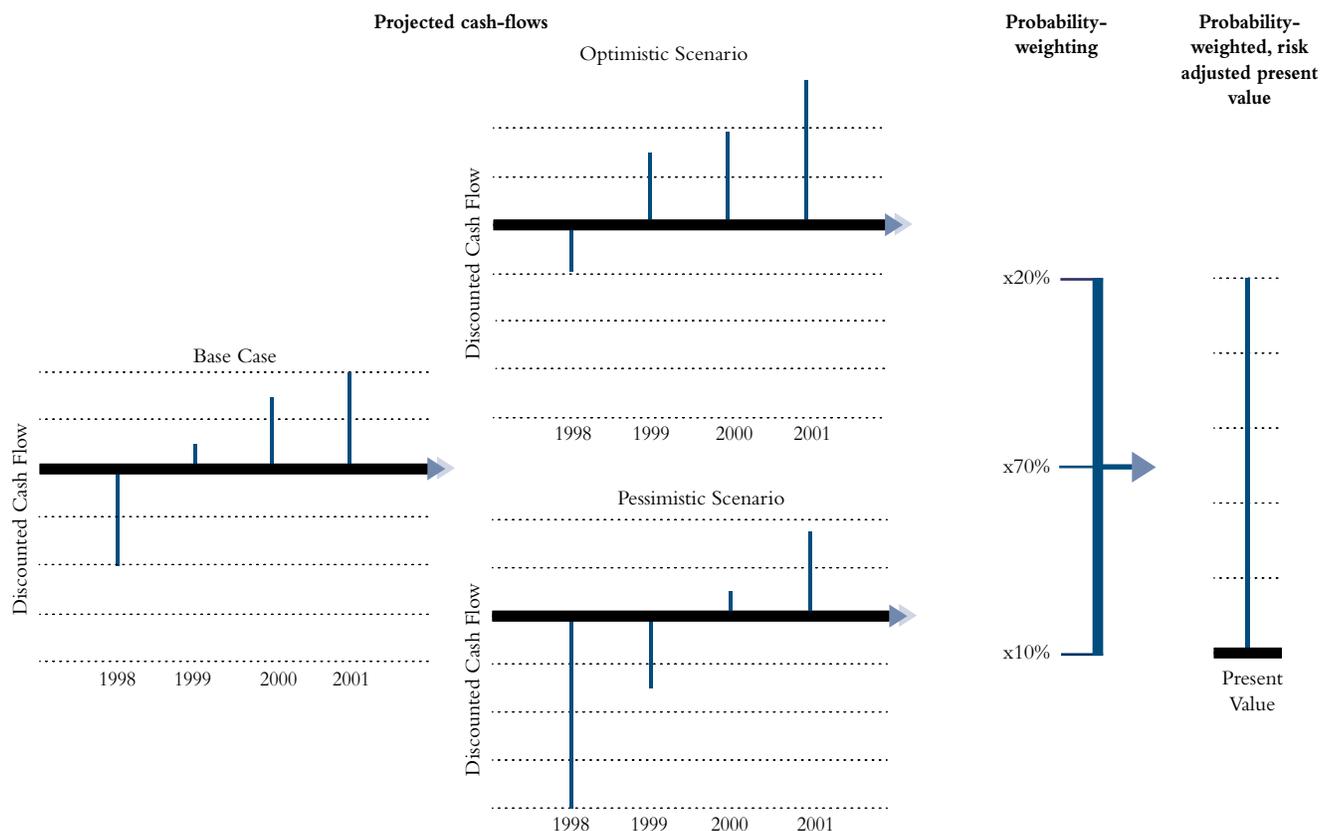
III.2 Innovation Option Prioritization

The outcome of the financial scenario modeling provides some powerful insights into the best paths for innovation investment. However, there are strategic elements that the quantitative analysis may not overtly reflect, or that are difficult to include in a present value. For instance, PharmCo may have a product that is losing its patent protection in the near future, thus opening it

up to new competition. The implication might be that it is necessary to invest in the innovation option with the shortest development cycle, even if the present value is lower than some others.

Strategic assessment of the innovation options requires re-visiting the broader strategic objectives laid out for the company. Managers should ask themselves whether collectively the innovation options they could invest in (which essentially represent the company's innovation strategy) will allow the broader strategic targets and imperatives of the business to be met. Making this assessment may be difficult, for the resources necessary for this kind of strategic review are often concentrated at the highest levels of the organization. The solution is to ensure, again, that innovation strategy and corporate strategy share an explicit link within the organization, and that the time of key personnel is formally dedicated to the ongoing process of developing both innovation and corporate strategy.

Figure 4: Probability-weighted, Risk-adjusted Present Value Calculation



By carefully balancing the quantitative and qualitative aspects of each innovation option we can arrive at a prioritized list of options deserving investment. It is now the responsibility of the manager to ensure that the results of innovation are realized in the form of new products and heightened profits.

Step IV: Implement and Manage the Innovation Strategy

The notion of a “pipeline” has always connoted an element of mystery: in the classic sense of the word, once something enters a pipeline it disappears from view until it emerges from the other end. *Step IV* seeks to create transparency around the R&D pipeline, and to establish concrete goals and timelines that allow a manager to control the flow of innovation projects.

The first and most important factor in successful implementation of the innovation strategy is to establish a detailed migration plan. Each organizational unit that is to be involved in the project — this includes production, sales, and marketing, not just R&D — should have a clear set of deliverables and timelines for turning the project into results. Multi-functional project teams should be established and empowered to facilitate decision-making and to drive each project through the R&D process. These teams must be sufficiently funded to be effective. In addition, investments may be necessary to alleviate capacity or capability bottlenecks.

Deliberate go/no-go hurdles and checkpoints need to be established for each research project, and progress should be measured periodically against these checkpoints. The checkpoints should be tied to the key criteria that would make the project a breakthrough value proposition. For instance, consider a project whose goal is to introduce a new ACE inhibitor with an improved safety profile and decreased costs. If at any stage the clinical data demonstrate that the efficacy profile is not superior to existing ACE inhibitors, the development should be terminated and the resources re-allocated, *even if the drug is proving safe.*

When the primary goals and pre-determined milestones of R&D are ignored, the result is wasted time and money, and the delay of other projects more deserving of scarce organizational resources. A common trap that companies fall into is a failure to eliminate projects that are not meeting pre-determined milestones and goals. The key ingredients to success here are discipline and objectivity: the discipline to cut off projects with “potential” if they’re not meeting their pre-determined goals, and the objectivity to avoid the political complexities that tend to inform many R&D-related decisions.

Summary: Driving Exceptional Returns Through Innovation Strategy

Innovation strategy has received increased attention in recent years, and it will continue to be a top priority of management as long as new product breakthroughs are the primary driver of value creation in the pharmaceuticals, diagnostics, and medical devices industries. We strongly believe that the allocation of R&D resources is a critical component in a company’s overall strategy, and that poor management of the innovation process can have huge long-term economic and strategic implications. In an industry where innovation and time to market are the key determinants of success, the companies who best manage their innovation efforts stand to gain at the expense of their competitors.

While there will always be a strong element of risk in innovation, the process of managing innovation should never be haphazard or risky. Instead, a holistic, balanced, and data-driven approach to prioritizing innovation investments can increase R&D efficiency and greatly reduce the risks of research bottlenecks, wasted R&D resources, or worse, product droughts.

The framework for managing innovation proposed here ensures that investments made in innovation are consistent with the overall strategy established by the company. This link between innovation strategy and corporate strategy must be established early and re-established often; the four steps of the innovation framework should be part of the ongoing strategic process, not one-time events. Only by linking these processes in an ongoing cycle can a company ensure that the innovation strategy it designs is the strategy that it actually executes.

Bain & Company: Strategy for Sustainable Results

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Bain & Company helps health care companies navigate a course to outstanding results. We work closely with motivated management teams to create a clear map, a goal, and direction for achieving not incremental improvements, but full potential returns.

Bain's global health care practice combines expertise, an industry network, and years of experience accumulated across all parts of the health care industry. Bain helps health care companies, including product suppliers, distributors, providers, and payers worldwide, select a strategic course and create a practical migration path to the goal.

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