

# BioPharm

INTERNATIONAL

November 2008

The Science & Business of Biopharmaceuticals



## Compliance Notes

### The Company at the Crossroads. *Part 2: Build or Buy?*

“Build or buy” is only convenient shorthand for a wide range of possible courses of action

In the previous installment in this series, we explored how emerging biotech companies should approach one of the most critical questions they face: what kind of company they ultimately want to be. Should they pursue the path of the idea factory that generates innovative therapeutic products and develops them to a point where they can be outlicensed to another company? Or should they become a fully integrated firm that takes innovations from discovery all the way to the market? Although the decision is a defining one, it is by no means the end of major decisions that either kind of company faces. Among those decisions, one of the most difficult and recurring is whether to build or buy critical capabilities.

Further, build or buy is only convenient shorthand for what in practice can be a wide range of possible courses of action, each of which involves differing risks and rewards. Consider the case of a rapidly growing, fully integrated firm that needs additional capacity. The company could:

• **Build:** Construct a new unit of its own.

An ad hoc or intuitive approach to weighing risks and rewards is simply inadequate for such a complex and important decision.

- **Buy:** Purchase a company, business unit, or facility that already has the desired capacity.
- **Upgrade:** Enhance the capacity of the company's existing units by installing new technology or extending a current line.
- **Optimize:** Enhance the yield of a current unit by cutting waste through Lean or Six Sigma.
- **Outsource:** Contract with a third party, such as contract manufacturing organization (CMO) or another pharmaceutical company, to deliver to specifications.
- **Leapfrog:** Stop investing in old processes and wait to spend money on next generation technology or processes.

There are also many possible permutations



Heilman

James Bonine, is a managing consultant, Conrad J. Heilman, Jr., PhD, is a senior vice president, and Siddharth J. Advant, PhD, is a principal, all at Tunnell Consulting, King of Prussia, PA, 610.337.0820, heilman@tunnellconsulting.com.

involving combinations of two or more of these solutions, which greatly multiplies the choices. In addition, many people in the organization are capable of generating even more alternatives.

To complicate matters further, assume that the company has faced similar decisions before and in both cases failed. On the first occasion, the CEO was sure he just knew the right thing to do. Nobody dared to protest and important showstoppers weren't brought forward until after the decision was made. On the second occasion, the opportunity disappeared while the decision process stretched on interminably.

Given the many choices and the possibilities for organizational dysfunction, one thing is certain: an ad hoc or intuitive approach to weighing risks and rewards is simply inadequate for such a complex and important decision.

### WANTED: A REPEATABLE PROCESS FOR HIGH-QUALITY DECISIONS

Fortunately, there is a way to avoid the pitfalls of intuitive decision-making and poor processes, find the best alternative, and retain alignment among all the constituencies involved in implementing the decision. This proven approach to decision-making has been successfully applied in thousands of complex and valuable decisions over the past twenty years.

This method is marked by two interdependent characteristics. First, it treats the weighing of risks and rewards as a science with adequate and controllable inputs, repeatable processes, and measurable results, much as in core scientific processes. Second, it accommodates the human factor by encouraging wide participation and providing the kind of neutral decision criteria that satisfies participants about the objectivity of the process.

In both the quantitative and human dimensions, this disciplined, structured approach offers many important advantages.

#### **Superior clarity in complex situations:**

Relatively inconsequential or uncomplicated decisions can of course be dispatched straightforwardly and without concern for issues of mobilization and alignment. Large, complex, value-laden decisions, however, require a process that can comprehend all of the complexities, as in the case of the integrated firm weighing the options for adding capacity. In this case, the issue of building or buying—and of all alternatives in between—involves a potentially significant capital expenditure, requires a complex weighing of difficult-to-compare choices, and risks that range from issues of adequate market supply to quality, and many more.

Somewhat paradoxically, the complexity of key decisions in biotech continues to grow faster as the industry matures. Smaller firms search for capacity while older players struggle under the weight of under-utilized capacity. Outsourcing drives work around the globe and costs-per-mile soar. Maturing regulatory scrutiny and upstart innovation are canibal cousins. New and increasingly capable technology requires increasingly complex implementation. The proliferation of technical specialties spawns whole teams with conflicting agendas. Gut instinct, vision, or turf protection, are no substitutes for the sophisticated methods of decision science that have been developed precisely to apply to such increasingly complex environments.

#### **Broad generation of alternatives:**

In biotech firms, complex decisions like build-or-buy usually cut across functions and disciplines

and can have implications that may not be obvious to the representative of any single function by itself. Having a single powerful individual dominate the decision blinds the group to a broader view. Excluding the inputs of important constituencies leads to the risk of hiding fatal flaws until it is too late to correct them. Further, critical functions and disciplines want their ideas and views considered. The decision-making process should therefore be designed to generate as many reasonable alternatives as possible from all interested parties. In our experience, the best mechanism for achieving those dual goals lies in a decision team broadly based across functions.

#### **More effective framing:**

Framing the decision means identifying the givens that must be taken into account and the level of detail at which the decision will be made. For example, it might be a given that the company's fundamental production technology will remain the same—new breakthrough technology is off the table. Lower-level details, such as whether to outsource administration, might be set aside to focus on the key decision—whether to build a green-site plant in an optimal location or retrofit an existing plant. Framing will also take into account the company's values—what it stands for and what it won't stand for. For example, if preserving the workforce is a company value, alternatives that outsource jobs would be out of bounds.

#### **Better information:**

The quality of a decision depends directly on the quality of the information on which it is based. The structured approach to decision-making includes mechanisms for ensuring that all usable and relevant information is collected, quantified

where appropriate, and weighted accurately. A decision team should ask itself if better information about any of the alternatives or the ability to pursue them might lead to a different conclusion. If the answer is yes, then the process needs work.

**Rapid filtering of alternatives:** The decision-making process should also be designed to quickly take the many possible alternatives and reduce them to the few that have the potential to create the most value. Otherwise, the process is likely to drag out unproductively in endless discussions of alternatives that don't merit such lengthy consideration.

Many alternatives are so similar that they are simply different settings on the same dial. The secret is to deeply understand the bookend-alternatives—those at the two extremes of the range of plausible alternatives. For the firm looking to expand capacity, those bookend alternatives might come down to only four: partnering with a CMO, buying an existing plant from another company, upgrading several small existing plants, or building one big new plant. This approach enables the decision team to focus on the most promising and

genuinely different alternatives.

**Strict comparability:** To ensure the optimal business decision and to satisfy participants that the process of prioritization of alternatives is fair and objective, a structured approach allows an apples-to-apples approach to comparability. Each promising and genuinely different alternative is measured in terms of its likely financial performance under risk and uncertainty. Typically, that measure is net present value (NPV) of cash flow. The final arbiter among alternatives is risk-adjusted profit, a language that cuts across differences and gets to the heart of the matter.

**Genuine alignment:** In many ways, the ultimate advantage of a structured approach to decision-making is the alignment of the team. Soliciting everyone's hypotheses and opinions and quickly prioritizing them through rigorous and objective methods of strict comparability satisfies all participants in the process, no matter their initial positions. Resistance is converted into appreciation for the most robust alternative. At the end of the process, the entire team is united behind the decision and ready to do their part to implement it.

By contrast, the intuitive approach can degenerate into a contest between several powerful advocacy groups in the organization and often results not only in poor decisions but also in triumphalist winners, resentful losers, and poor implementation. More than once, we've seen build-or-buy decisions that were supposed to produce important new capacity flounder because the decision-making process was short-circuited by favoritism and randomness. Or worse, the executive team simply announced a decision with great fanfare—all the greater because they had made and unmade the same decision several times before.

In an industry where companies must repeatedly make high-value decisions in the face of increasing complexity in technical, organizational, and regulatory developments, no biotech can afford to forgo the advantages of a rigorous decision-making process. Clearly, this is a province where decision-making exceeds the powers of intuition and requires the same science that tames the industry's other processes. In short, one of the most important decisions a biotech will make is what kind of decision-making process it chooses in the first place. ♦



## Discover the Value

Founded in 1962, Tunnell Consulting is a globally-positioned management consulting and implementation firm whose expertise improves the operating performance of each client we serve. With a strong focus in the areas of pharmaceuticals, biotech, biologics and medical devices, and supported by our deep industry knowledge and extensive scientific credentials, we integrate strategic, technical, process and organizational skills to design sustainable solutions for our clients.



### Headquarters

900 East Eighth Avenue, Suite 106 • King of Prussia, PA 19406 • ph 610.337.0820 • [www.tunnellconsulting.com](http://www.tunnellconsulting.com)

King of Prussia, PA

Washington, DC

San Diego, CA

San Juan, PR