



Life Science Leaders

The newsletter for executives in Biotechnology and the Life Sciences

September 2005

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The Odyssey in Quotes

“As we were getting Pharmacopeia off the ground over ten years ago, I observed similarities between the computer industry of the ‘70s and the historical structure of the pharmaceutical industry...monoliths, performing all functions from basic R&D to manufacturing to sales, as one business entity. Of course, the computer industry fragmented.”

Nolan H. Sigal, MD, PhD
Trellis Bioscience, Inc.

“At the end of the day, you can not outsource decision-making and responsibility.”

Bruce Bach, MD, PhD
Clinical Development Partners LLP

Fall 2005: A New Space Odyssey

The biggest challenge facing growing biotech is learning to play the value-creation game wisely – that is, learning to fund product development without giving up the long-term returns to development partners.

Partners have always been crucial in biotechnology, where companies are smaller and leaner, and often must “buy” rather than “make”.

Biotech is well acquainted with the many difficulties of outsourcing, such as IP security and control of the process.

Now let’s take our odyssey into some further questions:

- ◆ How much outsourcing is possible? Can we outsource leadership and innovation? What must we keep inside?
- ◆ Can we create low-cost, in-house processes that enable more to be kept inside? Are there other ways to staff and manage?
- ◆ Can we reduce costs and uncertainty enough to let smaller players enter the game?
- ◆ Can we in-license technical and strategic skills rather than, or along with, products?
- ◆ Does the company of the future only hire chiefs and outsource to Indians (chuckle)?

These are tough questions that I thought could provoke thought, so I decided to ask Dr. Bruce Bach to help start the discussion and break down a few concepts.

*Mari Paul
Founder, Life Science Leaders*

Executive Interview: Dr. Bruce Bach Clinical Development Partners LLP

Mari Paul: Bruce, you have managed life science companies large and small across many technologies. How do you see the “Make vs Buy” question?

Bruce Bach: “Make vs. Buy” means different things in different industries. The concept comes from manufacturing, where the market rewards you for efficient, high-margin production. That applies in medical devices, where it means restricting capital assets to the “must control” areas of the value chain, particularly for regulatory compliance.

Make vs. buy is entirely different in product development. Companies like J&J, Boston Scientific and Medtronic have strong internal development efforts focused on high value markets that demand product innovation. In the implanted stent market, these major players are willing to “buy” – to acquire companies – both for products and for innovative R&D staff. In pharmaceuticals, it can mean manufacturing efficiencies and/or sustained innovation - a very different flavor.

MP: What would you say are some of the “make vs. buy rules” in biotech and pharmaceuticals?

BB: I think the rules are changing, and they are hard to construct to begin with. Drug development is

famously uncertain. Development professionals are fond of saying “every drug is one of a kind.” But that does not mean you reinvent the process for each drug; rather that individual development efforts require different stops, reviews and insights to be successful.

These rules are generally not a single companywide program. In global pharma, we see separate value chain components (research, clinical development and finance) apparently acting semi-autonomously on make vs. buy. We also see companies buying both platforms for discovery-level innovation and assets that promise growth within existing markets; an example being the recent interest in vaccines by Novartis and others.

In product innovation, make vs. buy rules get more interesting and harder to handicap. In large, fast moving core markets like oncology, drugs in what once would have been niche indications are now reaching \$1 billion in annual sales, requiring a whole different cost/benefit analysis. Some of today’s biggest sellers in oncology looked like dark horses at various points in the value creation chain, and there was little that distinguished between big winners and terminated projects.

The critical success factor is often the tenacity of the project team and its ability to map a product’s features to an unmet market need. That defies make vs. buy rules. These sources of innovation and success are not necessarily a direct result of company size and can even come from the outside.

MP: *Those success factors aren’t linked to size, but would it help to customize some big pharma processes for smaller companies?*

BB: It is important to now consider critical mass, which can be defined in terms of knowledge, skills and relevant experience. Larger pharmas have the resources to get more shots at the goal. In order for smaller companies managing fewer shots on the goal to win, they must deploy the exact right

skills and measurements at each milestone step.

This is also about managing uncertainty. We can define the process, but do we really know the definitions? What really is critical? Or a core competency – especially when going from one stage to another? The same drug candidate looks very different when seen from a preclinical lens than a clinical lens. Preclinical insights do not always translate into the clinical successes. Managing across these value-creating inflection points is very important.

Take Genetech’s Avastin – it went into clinical trials for renal cancer and did not meet efficacy endpoints. By all rights, it should have been dropped there. Instead, it was tested in another clinical indication and approved on the basis of combined phase II results for metastatic colon cancer.

There are also always opposing pressures on the make vs. buy equation. Strength of internal advocacy alone can accelerate or doom a compound. And what about early clinical in-licensing? The compound is subjected to a whole new set of competing options and hesitations when it is acquired and not homegrown.

MP: *You mention good management through Inflection points as key to success – what else do you consider important factors and variables?*

BB: Really talented innovators have the ability to view things from two entirely different perspectives at the same time. They are good at answering the question: “How does what we know impact what we do not yet know?” That gets you through inflection points and is really important overall.

At the end of the day you can not outsource decision-making and responsibility. This means the biotech with the sustainable competitive advantage is the one that can build and maintain a culture that values knowledge and expertise applied to critical decision-making. That advantage

is even greater now that we have shortened views of where small cap and middle cap biotech play best in relation to the goalposts. It is a very important time to be able to choose the best preclinical candidates for early clinical development and to precisely iterate the fit between product characteristics and clinical populations to most efficiently address unmet clinical needs.

MP: *You also mentioned critical mass. How many bodies and buildings does it take to make someone perform tasks with enthusiasm and confidence?*

BB: Is “just enough” any kind of answer? “Critical mass” in my book means having everything you need for success at hand, when needed. Good management is the art of matching capabilities with opportunity. This does not imply picking small safe opportunities because you are more comfortable managing fewer talented people. You also have to build the team to the task, which is not easy but builds respect and confidence. Setting unique stretch goals for different people is easier said than done, but successful entrepreneurs can recognize who and what is required to get to the next step.

MP: *What one focal concept would you like to leave with us, Bruce?*

I think we have to keep this question in mind: “How do we find the resident or external skills that will best generate the next step up in value?” Harkening back to our example of drug eluting stents, I think our winners were able to manage the delicate balance of concurrent in-sourcing and out-sourcing. ❖

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