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# Shake Ups in R&D: It's Time to Try Something Different

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During 2008, a number of “big pharma” companies shook up their research and development units with bold moves designed to spark innovation, improve productivity and introduce a commercial focus into the scientific realm. In fact, of the top 10 global pharmaceutical manufacturers, six announced major changes to their R&D models and nine have made changes relating to the size, structure or focus of their R&D organizations.

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Most notable among these moves were:

- GlaxoSmithKline announced that it would split its drug development staff into smaller teams to mimic the biotechnology model. The initiative, the Center of Excellence for External Drug Discovery, is purposely designed to access “best-from-anywhere science” and to make objective choices about the products that will move forward to highly expensive late-stage development and commercialization

- A number of companies, including Pfizer, Roche and Wyeth, decided to shed or abandon early-stage research in selected therapy areas in order to focus their efforts on therapeutic areas where they hope to deliver more than an incremental gain over existing treatments
- AstraZeneca spun off its Swedish GI research unit to a syndicate of venture capital firms. The new entity, Albireo, is staffed by AstraZeneca researchers and AstraZeneca maintains a minority stake in the new firm

## The change

The earliest R&D models were fully vertically integrated, encompassing all functions from discovery through launch within the same company. That model was de-constructed from the 1980s onwards, as biotechnology spawned a raft of start-up companies that began generating the most innovative projects, but, in most cases, without the ability to launch them on their own.

This “dual innovation” model was not without its challenges nor did this dual innovation model address the underlying problem inherent in pharmaceutical companies—the fact that the R&D and commercial sides of the business had increasingly divergent goals. As a result, commercial departments have been driven to get market access at the right price—and that means developing products that please payers, as well as regulators:

- Because of the rise of the payer as a key customer, certain therapy areas hold no further commercial potential without the (unlikely or very expensive) discovery of a major breakthrough worthy of changing treatment protocols

- This payer-driven disdain for “incremental” developments in treatment of disease could, however, be counterproductive in some therapy areas, such as Oncology, where incremental improvements are crucial to the long-term therapeutic progression
- There is no longer room for a “build-it-and-they-will-come” mentality in drug development. Products will only be profitable if they address a true unmet need in the market and are developed with payers in mind
- Bigger is not better. Strategic intuition comes to fruition more easily in small, entrepreneurial groups than in big, monolithic companies
- Small, entrepreneurial units are saleable and open up opportunities for spin-offs
- R&D is no longer a “sacred cow” when it comes to trimming expenses

## The implications

Companies must resign themselves to the fact that changes made today will not deliver tangible benefits for another 10 years, simply due to the long development timeline. In the meantime, as large pharmaceutical companies proceed to adopt new models, they must:

- **Address and align the divergent motivations of R&D and sales/marketing:** given the realities of the marketplace, this means that it will be the development arm that must change. Thus, Health Economics and Outcomes Research approaches need to be integrated into the R&D effort from the outset
- **Manage expectations:** shareholders will need to be conditioned to the fact that R&D projects may have to take longer, cost more (in some cases to address smaller patient segments) and carry incremental risk
- **Lay to rest, finally and definitively, the “not-invented-here” syndrome:** if this is to happen, large pharmaceutical companies must foster greater flexibility and openness within their research units than have existed in the past

- **Foster an entrepreneurial spirit among researchers:** entrepreneurial qualities will be equally valued in both types of firms and there will be no place to hide for the researcher who is not suited to an entrepreneurial environment
- **Be open to new ways of working:** this includes forming partnerships—sometimes with competitors—at earlier phases of development

For their part, biotechnology companies must also begin to view R&D in a changing light and look beyond their big pharma customers. They can no longer focus solely on the “wittiness” or wondrousness of their technology, leaving the pharmaceutical company to figure out how to commercialize it. They must now look at projects with a critical eye, too, considering the changing decision-makers and their needs.

Because of the economic crisis, biotech companies have endured a harsh climate of scarce venture capital in the past year. In order to survive, biotech firms will continue to strike alliances with large pharmaceutical companies or secure financing from investors, but the attractiveness of their research projects will have to meet much higher standards. Now and in the future, funding will go to R&D projects with objectively weighed prospects for success in a changed environment.

With the steps that many leading companies took in 2008, it appears that the long-standing R&D model is at last undergoing an overhaul. And the R&D organizations of big pharmaceutical companies and biotech firms will be more than ever result-oriented rather than structure- or process-based.

Eventually, there may not be a single prevailing R&D model, but a series of R&D solutions for different therapy classes or companies. What is certain is that the shotgun approach of therapeutic omnipresence belongs to the past, while laser-precision focus and selectivity are taking hold across the industry.

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