

Putting a new spin on R&D assets in the pharmaceutical industry



'Can some assets of major pharma be better exploited in a different business environment?'

The seemingly inexorable merger and acquisition trend in the pharmaceutical industry has several origins: the quest for economies of scale resulting from global marketing, distribution and manufacturing, the savings associated with integrated transnational operations and, perhaps, the need to compensate for revenue loss when major products go off-patent. Then there is the argument that the intrinsic complexity of discovering, developing and marketing novel therapeutic agents places the industry in a unique position among human activities to which a special scale is appropriate. Few other enterprises, so this argument goes, place such demands on the acquisition, analysis and practical orchestration of specialized information. The computer and aircraft industries perhaps do compare, but analogies drawn from the evolution of other industries require critical scrutiny. For example, the next steps in the consolidation of the global pharmaceutical industry are widely thought to be a merger/takeover to create 'mega pharma' entities (perhaps six or seven), each with a double-digit share of the world pharmaceutical market.

Although potential improvements in corporate functions, marketing and sales are important, the impact of size on R&D productivity is more controversial. Major pharma now finds that billion-dollar R&D budgets are insufficient to guarantee the marketing of the 1.5 new chemical entities (NCEs) per year that the organization needs. After a merger of equals, with a doubling of the R&D budget, the new mega pharma will inevitably come to demand three or four NCEs per year. That may be possible if it is the development process that is holding up productivity, but it is less clear that increasing the size of the discovery effort will increase the discovery rate.

Invention – a quantized phenomenon involving human creativity – is not reliably linked to size. Most large companies realize this and look to alliances to enhance discovery opportunities.

Invention and creativity

Nevertheless, increases in discovery productivity have occurred and the improved quality of development candidates that has resulted from the quantitative advances of combinatorial chemistry and high-throughput screening are beginning to impact the pipelines of some companies. What is lacking is convincing evidence that inventiveness improves within an ever-increasing size of R&D infrastructure. Inventions come from the right people applying the right variants of the right technologies to the right therapeutic target at the right time. The danger within the megacorporation is that the right people's technological vision, therapeutic area commitment, creativity and scientific acuity will be diluted. The diluting factors will, of course, be the committees, working parties and task forces engaged in reorganization, analysis, prioritization and resource allocation of the dozens of diverse research projects that the megacorporation will deem necessary in order to spread the discovery risk effectively.

So is it all about focus? The answer is 'yes, and about people'. This duality of focus and entrepreneurial drive is widely assumed to be the reason behind the remarkable inventiveness shown by many small start-ups. The challenge for mega pharma is to reproduce these conditions and thus prevent the sacrifice of invention to the innovation drive that speeds and expedites the assembly line from development drug candidates to marketing and sales.

One option for mega pharma is to try to give a degree of self-determination to small, specialist teams of identifiably inventive scientists in-house, and to resource them adequately even in the face of ever-demanding development portfolio needs. We argue that this strategy is rarely successful, largely because in a major corporation, promotion and career advancement depends to some extent on visibility – in practice going to those involved in critical path activities.

Alternative strategy

An alternative strategy to the specialist group in-house is to introduce business flexibility in the organizational structure.

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One model envisages the parent company as the central development hub of an organization surrounded by networks of alliances, collaborations and new satellite companies – all with different linkages to the parent and with varying degrees of independence. Something like this organizational structure is in place in most major companies, largely driven by the need to fill gaps in the overall skills base, the need to change or upgrade core competencies, and the need to divest areas of expertise or whole business areas that are peripheral to the changed mainstream.

The spin-out company as a business strategy

One potential business model differs fundamentally from most of these strategies. In its simplest form, it is a process that is proactive and purposeful. The model is that of the spin-out company involving early-phase research assets. Major pharma usually evaluates its research portfolio from the perspective of linkage of activities to core competencies and critical paths; we believe that too rarely it evaluates its research portfolio from the perspective of whether assets exist that could be exploited better in a different business environment. However, it is understandable that this is not common practice. It can be costly in terms of management time within financial, legal and personnel departments. It also requires courage on the part of the research manager who has held responsibility for the overall balance of the research activities; courage to respond vigorously to suggestions that non-core activities should be spun-out and courage to deal with the turbulence generated within the local scientific community – a phenomenon not unique to spin-outs but shared also with all forms of outsourcing.

These initial problems will be readily overcome when, as we foresee, a cultural change pervades major pharma such that a research manager's duty, underpinned by formal objective setting processes, includes a commitment to assess all research, not only for contribution to core activities but also as potential assets for spin-out initiatives or as currency with which to 'do deals' with other companies. The discovery function may even become a revenue-generating centre rather than a cost-centre. This is not an unrealistic vision; small companies already operate in this way, using research assets as currency in setting up deals and alliances.

Key criteria for potential spin-out topics

Our experience suggests that it is already possible to define some key criteria that should be applied to potential spin-out topics.

- The science and technology must fire the imagination of investors – it must provide a 'buzz'.
- It is likely to be visionary, leading-edge science yet sufficiently defined to show that the basic ideas can be reduced to practice with the promise of application over several potential product areas or of creation of new platform technologies for major pharma.

- There may, even early on, be a hint that the technological basis of the work could develop into tomorrow's core competencies for the industry and that its product portfolio has the potential to address unmet medical needs, albeit in niche markets.
- The discoveries must be supported by patents and a forward-looking patent-filing plan.

It is extremely difficult to put a monetary value on early-phase research. Without patent protection, value becomes even more intangible. Equally, the scientific team is a key component. They must believe implicitly in their science, they must be willing to commit their careers to its exploitation and they must have the entrepreneurial, risk-taking drive. There are few instances in which the science and scientist characteristics coincide but, hitherto, scientists in the industry have not been expected to consider entrepreneurial careers. When the two qualities co-exist things can move forward; each of the three key players, parent company, spin-out group and investors is critical to success, but each will have a different perspective.

Incubation facilities

We will not discuss here the details of the spin-out process, but one factor is worthy of comment because it proved to be the single most important factor underpinning our success. This was the offer by our parent company of 'incubation facilities' – functional laboratories and supportive infrastructure for a sufficient period to allow the spin-out team, still full-time employees of the parent company, to organize and focus their science and prepare a business plan. If our experience of the value of incubation can be generalized, it augurs well for the success of those universities who have taken on board the provision of such facilities to encourage and nurture groups who wish to spin-out assets from academia.

Partnerships and networks

A critical interdependence is developing between major pharma and start-up enterprises, each side contributing an essential role in the complexity that is drug discovery. It is a partnership in which the dual needs of innovation and invention can come together for mutual gain. Spin-outs are a small part of this bigger picture, but probably growing in number and impact.

The most frequently asked question of a spin-out enterprise is: 'why do you believe your science and technology will be successfully exploited from within a small company when, even with the massively resourced R&D of major pharma it was not deemed to be a key asset?' Our answer is a simple one: 'in the competitive environment of major pharma, it may prove impossible to get exploratory research on the agenda. For the small biotechnology company, it is not only *on* the agenda, it *is* the agenda.'

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