
Editorial: R&D in biotechnology – The management challenges

THE CHALLENGES

Biotechnology companies are under intense scrutiny and unremitting pressure from shareholders and investors to convert their costly R&D inputs into value-creating outputs. Yet the tools and techniques for influencing and managing R&D productivity are often weakly developed and rarely fully deployed in many early stage and mid-cap biotech businesses.

There are many reasons for this, not least because biotech companies often have a strong science-led heritage and ethos, where the anarchic elements of research are encouraged. The disciplined tools used for research management and product development in big pharma, diagnostics and medical technology companies are not at first seen as necessary, and are then overlooked as the company grows. In fact, it is argued here that there is considerable opportunity for biotech managers to strengthen R&D performance and productivity through deploying more robust management tools that enhance strategic, organisational and operational processes. These will lead to better allocation and use of resources, and ensure the right products are developed in the right way – at the right time.

What is best practice for efficient and effective R&D for an early stage or mid-cap biotech business? Too much control and bureaucracy stifles creativity and slows down decision making, particularly in the discovery phases. This was purported to be the reason why GlaxoSmithKline created smaller working units in its discovery operations, reorganising its centralised R&D into six therapeutically focused and more

autonomous Centres of Excellence in Drug Discovery.

Too little control leads to inefficient use of resources, particularly as focus moves from research to development. Researching the wrong projects, poor communication, missed milestones and failing products that bounce, with increasing desperation, from one clinical application to another are some of the symptoms. Sadly, these have been common reasons why some promising biotechnology companies have not lived up to early expectations – and why their products have fallen by the wayside.

THE SOLUTIONS

Each business and product portfolio is different and it is important to diagnose R&D management problems carefully before trying to fix something that may not be the root cause. It is certainly not possible here to address all the factors that should be considered to achieve optimal R&D performance, but it is helpful to consider the analytical framework. Two questions must be addressed to the R&D function: ‘Are they doing the right things?’ and secondly ‘Are they doing them right?’ The first is actually a question of strategy and portfolio, while the second concerns issues of organisation (including culture), resources and the processes that enable R&D to deliver the necessary outputs efficiently.

STRATEGY

Taking strategy and portfolio first, these are of course the *raison d’être* of the business, that define its direction, therapeutic or market focus, products and services and business model. Excellent

science focused on the wrong product opportunities is all too common in biotech – this often arises because the business has been built on a technology opportunity looking (sometimes in vain) for clinical applications. Here, setting the right focus on clinically relevant, distinct and protectable product opportunities, with attractive market sizes and growth rates – with promising health economic and reimbursement opportunities at the start – is key.

Gut feel and collective judgment may turn out to be good management tools when the portfolio is small, but more formal techniques such as decision trees and simple options tools are valuable as portfolios grow. These tools enable risk-adjusted values to be attributed to each commercialisation option, allowing the portfolio to be visualised and valued. The question of ‘are we doing the right things?’ then becomes both easier to answer, and easier to re-address as market dynamics change and product development proceeds.

PROCESSES

Once the direction is set, the key job in R&D is to ensure that the necessary processes are in place to deliver the strategy, backed with the appropriate resources. These should of course be set within an organisational structure that suits the model and culture of the business.

One process-related area that merits particular attention is effective and transparent decision making. This encompasses which projects to include in the portfolio, and how to proceed or terminate studies as they progress through the R&D programme. Best practice here is about establishing clear objectives, responsibilities and a business case for each project with defined milestones and robust go/no go ‘checkpoints’ or gates. Monitoring and review processes need to overlay decision making to ensure key scientific and clinical milestones are on track.

Killing a failing project is always

difficult – especially when the appetites of investors and stakeholders have already been whetted. But ‘failing weaker projects earlier, pays dividends later’ has now become the mantra of big pharma. Biotech must embrace this too, even though pipelines are smaller and each candidate is accordingly more precious.

ORGANISATION

Organising for optimal R&D must reflect the strategy and business model. Most smaller research-led biotechnology companies run projects with teams from different disciplines. Here it is important to design the most efficient organisation that maximises innovative synergies (eg between assay developers and medicinal chemists), while ensuring efficient management of resources: time, people, money. As biotech businesses grow, links with functions become important not least between sales and marketing and R&D. The matrix versus group/team-based structure is the subject of perennial discussion in many R&D-based businesses and biotech companies face the same issue. A major challenge is the lack of shared experience and information to guide growing biotech companies on organisational best practice, in comparison with, say, big pharma or other manufacturing sectors. This is an area where non-executives and industry groups and forums can play a useful role.

RESOURCES

The final part in our simple framework is resources, and their efficient and effective deployment. Since salaries will be a major part of the research budget, ensuring the right people are hired with the right skills and then deployed on the right projects is a key part of achieving efficiencies. Rigorous checks and balances in assessing the need for new R&D hires are vital. Simple benchmarking can be useful: ask ‘how much do we spend on R&D per R&D employee, compared to our peers?’ Opportunities for outsourcing, or using contractors for repetitive, cyclical work should be considered. Developing in-

house metrics for productivity and comparison of R&D spending against peers is a good way of periodically checking that efficiency and productivity are on track.

Once products move to the clinic, development costs grow dramatically and a new set of resource questions emerge that return us to strategy and the areas of partnering and licensing that cannot be addressed in the scope of this editorial.

CONCLUSION

In conclusion, there are many ways for the senior managers of biotech companies to achieve *better* practice, in relation to R&D, even if *best* practice in biotech has yet to be well defined and validated. As

the business grows, robust systems for R&D management become essential, not just to help allocate resources, but also to organise the company and to minimise risks and exploit the product opportunities. Managing these opportunities using better R&D practice will help to ensure the sustainability of the business and deliver the growth and success that shareholders and investors demand.

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