Shaping Pharmaceutical Strategy
The Elements of a Winning Strategy in R&D
Catenion

Prepared by: Markus Thunecke and Matthias Krings

Introduction – The Problem of Defining Success in R&D

R&D Strategies come in different shapes and sizes. Some companies focus their efforts on therapeutic areas or indications, some on drug formats, some rely on scientific excellence and breakthrough innovation while others are obsessed with productivity and efficiency. In the complex world of drug discovery and development it appears unlikely that there is a "one size fits all" best practice when it comes to strategy. Quite to the contrary, sceptics will argue that pharmaceutical R&D Strategy is often defined ex post to rationalise successes that in many cases have been based on serendipity. However, to quote Pasteur "Chance favours the prepared mind" and it is time well spent to discuss the question "What defines a prepared mind in a strategic sense?", or more simply put – what are the elements of winning R&D Strategies?

It all starts with a fundamental question, namely what defines success? Again there are several possible angles with the ultimate measurable outcome being the number and lifecycle value of products that a company has generated out of its own R&D efforts.

However, there is one significant problem with such an analysis! Even if the definition is correct, the results that we see today are the output of R&D Strategies from 5–15 years ago. In many cases companies have gone through several mergers and changes in strategic direction, so it is difficult to create a link between cause and effect.

An alternative approach, and more direct link, would be to measure the strength of the current clinical pipeline. Indeed it is possible to quantify this strength as the risk-adjusted net present value divided by the total R&D spending in previous years. Although the timing issue is less pronounced with this indicator, there remains the well-known problem of determining commercial potential of a compound. Here the uncertainty can be substantial; especially when one needs to make forecasts for novel approaches that will shape or establish a market and not simply enter an already existing market. It is even more complicated, because the available forecasts used for cross-company comparisons usually stem from consultants or analysts outside the company who have to rely on incomplete and imperfect information.

In order to try and circumvent this problem, one could simply take the number of projects in a pipeline divided by R&D spending, but of course this measure does not capture value-creation potential since a future blockbuster can have the same value as ten niche products. In addition, the problem of differentiating between early-stage and late-stage, between therapeutic advances and minor improvements or line extensions is not addressed.

Top Performers and their Strategic Approaches

One could easily write a PhD thesis about the question of how to best define success in R&D, but in this commentary we have chosen a pragmatic, composite view of the afore-mentioned indicators plus qualitative assessments stemming from industry publications such as the "Top Ten Pipelines" as defined by "R&D Directions" magazine. Based on this approach, companies such as Roche, Genentech, Lilly, Novartis, GlaxoSmithKline, Wyeth, and Sanofi-Aventis are top performers.

The strategic approaches that these companies are pursuing are very different:

Roche is the prototype "networked" R&D organisation that relies heavily on strategic partnerships (with Genentech, Chugai, and others), has a strong focus on high-value specialist drugs and is engaged both in small molecules and

biologics. It is also the company that is most aggressively positioning itself in the emerging space of Personalised Medicine.

GlaxoSmithKline is an organisation that tries to capture the advantage of economies of scale while maintaining autonomy and a "small company feel" within their CEDD structure, complemented by aggressive in-licensing.

Wyeth has adopted the concept of "Managed Research" with its stringent controlling metrics and strong focus on productivity.

Lilly is about scientific excellence and networking, with a strong presence both in small molecules and biologics.

These few examples already demonstrate that it is difficult to identify a clear "strategic best practice" even among the top group of performers.

Two Archetypal Schools of Thought

The strategies of individual companies may differ and are subject to frequent change or modification, but at the all-important level of values and beliefs there is usually more continuity for historic or "legacy" reasons. Values and beliefs are deeply engrained within an organisation and with its people; they are the result of a long process of socialisation and organisational development. Within the pharmaceutical and biotech industries, we have identified two archetypal schools of thought located with their respective sets of values and beliefs at the extreme opposites of a continuum.

At one end of the continuum there is a school of thought that we call "Creativity-led". Its values and beliefs express that scientific excellence and a certain degree of freedom will ultimately lead to breakthrough innovation. Genentech and other biotech companies are prime examples of this school of thought.

We call the school of thought at the other end of the continuum "Productivity-led", since it has its roots in the belief that tight management, goal-setting, cost focus and controlling will lead to more predictable innovation patterns. Propagators of this school often talk of the "innovation engine". The new Wyeth organisation is a good example for this school of thought and this concept is most prevalent among big pharmaceutical companies.

It is important to note that both schools of thought require elements from each other to be successful, especially at the level of organisational implementation. The "Creativity-led" model requires processes, controlling, portfolio management, etc., whereas the "Productivity-led" model also requires excellent scientists and creativity. But their main sources of competitive advantage differ. Many people will argue that as organisations grow bigger they will automatically move from "Creativity-led" to "Productivity-led". This view is primarily focused on the level of the organisational implementation, where most companies will require stringent processes as they grow bigger. At Catenion we would argue that there are an increasing number of large organisations that, at the level of values and beliefs, are located more on the side of "Creativity-led", while their organisations have almost by default been designed towards productivity. For them the challenge is to combine the elements of "Managed Research" with approaches that foster and stimulate breakthrough innovation.

So which approach is more successful, "Creativity-" or "Productivity-led"? Both seem to have their merits; the latter should lead to a more predictable flow of projects through the pipeline, the former, while presumably more erratic, may produce more major innovation. In our view, given the uncertain data base on which to base a judgment, it is a pointless discussion to try and determine which value set or school of thought is "better" and which should serve as a role model for other companies.

The Five Elements of a Winning Strategy

The real question is not which strategy model is best, but how to ensure successful implementation of "Productivity-led" or "Creativity-led" strategies.

In our experience, at least five elements need to be fulfilled:

1. Consistency – no matter how a value and belief set is defined, the resulting strategy as well as the organisational set-up and processes need to be consistent with it; execution is crucial. For example if a company wants to focus on breakthrough innovation it will need to attract the best scientists in a particular area. This implies a culture that is particularly attractive for these types of scientists – they will want to publish, they will want to network, they will want freedom to be creative, etc. The HR department needs to understand their needs and behaviours to tailor programs accordingly. Consistency also implies that R&D and company strategy have to fit together.

2. Connectivity – pharmaceutical R&D Strategies do not thrive in splendid isolation. Connections that an organisation has developed internally and to the outside world through partnering, collaborations and simple day-to-day interactions are essential in a field where no single individual, group or company can develop or maintain all the required knowledge to be successful. The pace of progress in science is simply too fast. This has become particularly important with respect to academic connections since many organisations view commercial/academic partnerships as being central to success.

3. Perseverance – many companies change their strategic direction every two to five years. This is commonly due to management changes and increasingly because they are involved in major partnering or M&A. This disruption of an organisation is problematic in an environment where it takes five to ten years before the outcome of a strategy can be observed.

4. Flexibility – even if one defines a strategy and sticks to it, there needs to be flexibility to change gears or adjust the direction as the environment changes.

5. Sense of purpose – although this is last on this list, it is probably the most underestimated element in terms of impact. All great organisations have this sense of purpose, which drives employees to go the extra mile. While the credo "we are doing the best for patients" is often cited, only few organisations are able to live up to it without ending up in a cynical mode. This is often due to the lack of consistency with the actions that a company is taking for example in its marketing practices.

Genentech – An Example of a Winning "Creativity-led" Strategy

Not too many companies have been successful when measured against the five criteria. Genentech is one example that fulfils the criteria and at the moment its success speaks for itself.

Genentech's strategy and organisation is consistent: As a prime example of the "Creativity-led" school of thought it attracts the top scientists and has dominated the lists of most popular places for life science PhDs. Also consistent is the culture of providing enough room and unmanaged space for creativity. Genentech's focus on strategic goal setting (5 x 5 goals), strong portfolio management and operational excellence do not conflict with the company's belief in the value of creativity.

Connectivity is ensured through numerous collaborations and active participation of Genentech's scientists in the academic community as well as strong publishing activities. Despite the fact that Genentech has a strong internal R&D, it should not be forgotten that several of their products/projects stem from external sources.

Perseverance is one of Genentech's strengths: The company has maintained its course even during times when it was criticised for a weak pipeline and a high R&D spending rate during the 90s (to be fair, part of the credit has to go to its majority shareholder, Roche).

Genentech also displays a strategic flexibility as it has expanded from a history in classic protein drugs to

monoclonal antibodies and is now carefully entering into the world of small molecules through its OSI partnership on Tarceva.

Sense of purpose is probably an area that sets Genentech even further apart from the rest of the sector. One gets the feeling that its scientists are really on a mission to develop great drugs for patients with severe diseases. It is a quality that is hard to define, but one knows and feels its presence immediately.

Wyeth – An Example of a Winning "Productivity-led" Strategy

A company at the other end of the spectrum is Wyeth. It has successfully revamped the way it does R&D from an unfocused, and some critics would say, ineffective organisation into the shining example of a highly productive R&D "machine" that has the goal to deliver two NMEs per year starting in 2006. Unlike Genentech it has not yet proven that this strategy will actually turn out great products, but the vital signs reflected in its pipeline are certainly encouraging.

Consistent with its focus on productivity is an extremely effective use of resources, reflected in strong portfolio management, goal-setting and process excellence. Wyeth has the goal to generate INDs at less than 50% of the industry's average cost while maintaining a high level of quality. Wyeth is also creating accountability by linking the performance of scientists to salary and bonus development, both upwards and downwards. All this is captured in pre-negotiated goals and scorecards.

Connectivity is a major theme of the "new way of working" at Wyeth with its strong focus on teamwork, sharing ideas and creating bonds internally. In addition the company has developed several important strategic partnerships.

Perseverance is a quality that is hard to assess due to the novelty of Wyeth's strategy, so we await a verdict with much anticipation. In the past, the company has gone through several M&A activities, and the result was a mixture of approaches and strategies with Wyeth, Lederle, Ayerst and Genetics Institute all contributing.

Flexibility is definitely a strength as the recent revamping of R&D indicates. Also, the company was one of the first to fully embrace the potential of biopharmaceuticals, and that in spite of its small molecule heritage.

Sense of purpose is always the most difficult to define but one certainly gets the impression that Robert Ruffolo and his team are on a mission to prove that they can "pull it off" and this has the potential to create a strong resonance throughout the organisation.

The Strategic Journey Starts with a "Simple List of Questions"

What does all this mean for Senior R&D-executives who are constantly confronted with requirements to change or adapt their strategies? A winning strategy is not about copying what others might be doing or an exercise that is disconnected from organisational capabilities and portfolio. So what is it, then? In our view, it is a journey that starts with a simple list of questions such as the following:

- What are my organisation's values and beliefs? Where are we located on the continuum between "Creativity-led" and "Productivity-led"? Do our values and beliefs give us a competitive edge?
- How consistent is our strategy and organisation with our values and beliefs? Does our strategy and organisation reflect our strengths in the portfolio and our organisation's skill-set? Do we have the right level of operational excellence even if we belong to the "Creativity-led" group? Do we have the right level of creativity and unmanaged space if we belong to the "Productivity-led" group?
- How connected are we internally and externally? Are we leveraging our economies of scope across organisational and epistemological barriers as well as our economies of scale?
- Are we perseverant enough as a company? How many different strategies have we had in the last ten years? What has worked, what has not worked and are we changing direction too often and too fast?

- Are we flexible enough to learn and adapt if we find out that something is not working? How good are we in making portfolio decisions?
- What makes our team of scientists want to go the extra mile? What is our sense of purpose as an organisation? Does it go beyond often cited platitudes, can we really feel it? How full is our car park after 6 pm or during weekends?

After going through this list, the first question is where one sees the biggest need for change? If that need is at the level of values and beliefs it is going to take a long time of change management to steer the organisation into a new direction. This can easily take years and will sometimes require replacing the entire management team and big parts of the organisation. This is certainly not something for the fainthearted.

At Catenion, we believe it is a lot easier to adapt or newly develop a customised strategy. In our experience, if the new strategy is based on the principles laid out in this commentary, it will have the best of chances to, per Pasteur, "prepare the organisation's mind" and ultimately therefore turn into a "winning strategy".

Berlin · Headquarters

Catenion
Hausvogteiplatz 12 · 10117 Berlin
Germany
phone: + 49 30 20 63 9960

Dr. Markus Thunecke · Senior Partner
email: markus.thunecke@catenion.com

Dr. Matthias Krings · Senior Partner
email: matthias.krings@catenion.com

Arno Heuermann · COO
email: arno.heuermann@catenion.com

London

180 Piccadilly · London W1J 9HF
United Kingdom
phone: + 44 20 7917 9511

Christian Elze · Senior Partner
email: christian.elze@catenion.com

New York

405 Lexington Avenue · 26th Floor
New York · NY 10174
United States
phone: + 1 917 368 8376

Florian Jehle · Principal
email: florian.jehle@catenion.com

www.catenion.com

Catenion GmbH, Hausvogteiplatz 12, 10117 Berlin – HRB95394 B, Geschäftsführer: Dipl.-Ing. Arno Heuermann