

Drug Pipeline Sustainability

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What does the Drug development industry have in common with every other major industry sector? When it comes to product development, on the surface, very little! Nostrapharmus explores this in more detail.

In 2006, nearly 500 products were launched every day across all other sectors, that's a 50% increase from 2005 and almost 100% from 2004, yet in that same period the combined might of the Pharmaceutical industry, the greatest R&D force both by numbers and dollars spent launched just 21 active substances. Nostrapharmus notes that what makes this picture even bleaker, is the fact that spend on R&D has increased annually without fail, in fact, the industry spent 100% more in 2006 than in 2000, yet launched half the active ingredients. The spending increase is inexorably up, the rate of new releases declining.

So is the industry failing to innovate, are there structural impediments in the industry that are driving down the rate of innovation, or has the industry simply run out of good ideas?

Some would argue all three are true, yet this hides the real truth. Products that are launched are no less successful than the past, the conversion rate at which actives are taken to market is about the same as the past, but regulation changes have slowed the pace at which they enter the market, and whilst the last 30 years of research avenues have steadily disappeared, new techniques and methods are appearing.

In fact all the evidence suggests, whether RNA based chemistry, computer modelled drug discovery or even Raman spectroscopy and its ability to investigate drug delivery in completely new ways will all open as yet undiscovered vistas into the new cycle of drug discovery. We are at the beginning of the next wave even as we end the last wave.

The future is already here

The real danger is that companies will fail to take advantage of this new wave and without stretching the metaphor too far, be left on the beach while competitors sail out to lands anew.

So, how should companies identify the best routes; where to invest, how to combine the work in all these fields to ensuring that they are part of the next wave?

No single company can ever hope to be at the leading edge of all new technologies and techniques, nor can a company expect to successfully integrate such knowledge easily into their existing structure. In fact, history has shown that mergers and acquisitions have, at best, a mixed success rate and rarely achieve any step change in a company's innovation capability. More often than not, companies can only hope to stand still competitively, or maybe move to adjacent markets.

Knowing that they must invest in often small unproven companies, investigating the leading edge, pharma have invested huge sums on Biotechs and Gentechs, what they have failed to do is to upgrade the existing organisation with the flexibility and attitude required to take advantage.

Agility is the key

The rate of innovation of an organisation is proportional to the ability for people to participate. Few would argue that the Pharmaceutical industry is a model for open and successful participation, and

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with new techniques being ever more specialised, and with personalised medicine, the scope for a scattergun of success is ever declining.

What we need are companies that are designed to increase the level of participation, both from existing stakeholders and, as yet, unknown participants. Companies have ideas about where new discovery will come from, but as we enter this next stage we can't be sure, and so we need to be open to new ideas and, potentially, very disruptive technologies.

The challenge is balancing the strict and often rigid regulatory models against a fluid involvement of ideas and the need for companies to quickly move to exploit as yet unknown directions.

Nostrapharmus sees a hazy future for which companies need to be prepared and says: 'Companies will need to have a structure that provides a core and stable platform around which new ideas can be assimilated, understood and, where relevant, pursued further or discarded. The cost of travelling the wrong route is astronomically greater than being late, but being right.'

Getting started

Companies need to be able to manage intellectual property in four key scenarios:

1. A drug they develop: companies manage this now
2. Research they acquire: whether buying a company or expertise; how quickly is this integrated into the business and benefits are generated?
3. Research that they share: specialist knowledge of others may not be for and companies will need to find ways of participating with companies that are maybe not financially comparable but knowledge wise are equal or even ahead
4. Research they release to the others: you can't take something further, but can a competitor or a new start-up? Is it better to make something out of someone else's success than gain nothing of your own? This is likely to be one of the biggest challenges the industry faces, but companies may have to learn to give in order to get

All of this requires the ability to work across complex boundaries, collaborate in both an open and trustful manner, and development of new models for sharing risk and reward. The Pharmaceutical industry is just not ready to manage and operate in this manner. However, the failure to innovate, not just products but their approach, is likely to leave them spending much more and achieving very much less.

Nostrapharmus says: 'There is no simple Innovation 'ON' switch. Building an innovative company takes time and clear direction, synchronisation from the centre, cross-boundary collaboration, and changes to the organisational structure. To ensure success leaders need to put in place:

- Vision
- Funding
- Policy
- Education
- Culture

Starting now will mean that companies are ready for the time when this new generation of technologies becomes the norm rather than the new.