

**In the next 2½ years, 50% of the world's Top 10 bestselling drugs will lose patent protection in the US. Fewer patents mean lower profits, so M&A is absolutely key to pharma's future, say the team at Celerant Consulting's Private Equity Centre of Excellence. But the way companies come together must be geared to produce ultimate profitability.**

# Looking Beyond The Pipeline:

**New drivers, new approaches to M&A.**



**W**hen the collapse of the financial industry in 2008 plunged the world into a global recession, the world of corporate transactions felt the impact in dramatic fashion. In the pharmaceutical industry, the sudden wariness around M&A could not have come at a worse time: the sector was on the brink of a new age. Globalisation and regulatory pressure were shifting the environment from one of a healthy cash flow ruled by big pharma to a more compliance heavy, cost conscious industry.

M&A is now returning with a vengeance - although the game has changed since the heady days of the early 2000s. Consolidation of pharma giants continues, but the targets have changed in large part due to patent expiry concerns. As the industry contracts, insuring that mergers create the intended value is of critical importance: there is less room on the margins and therefore greater focus on the process of bringing 2 entities together to achieve a new level of prosperity.

The new industry paradigm is typified by the recent \$20bn takeover of Genzyme by French

powerhouse Sanofi-Aventis. The traditional drivers remain as Genzyme will provide new product potential to a pharma with wide ranging access to markets across the globe. The key difference lies in the type of product: Genzyme's prowess in biotech means that they will contribute new science and most likely hyper-targeted drugs - not the next blockbuster. Indeed, Sanofi CEO Viehbach noted the main reason for the merger was not about cost savings, but to tap into Genzyme's genetic-disease drug niche. Pharma insiders and industry watchers have long known that companies were facing a torrent of patent expirations in the first half of this decade. And while expiring patents is nothing new, a lack of new drugs earning regulatory approval is. Companies are increasingly being forced to take a different approach to the pipeline in order to stay competitive and profitable.

#### Pre-empting the patent plateau

Researchers at UCLA have declared pharma to have reached 'the end of the blockbuster drug era'. Fewer and fewer drugs will see \$1 billion in sales, and if companies are to keep their profit margins up they must have more drugs in their portfolios.

*'Having a proper integration structure will ensure that both sides are fully prepared to hit the ground running.'*

The primary culprit for the death of the blockbuster is the emergence of low cost generic drugs that are eating up market share as patents for big market products expire. Within the next two years half of the top 10 bestselling drugs in the world will lose their patent protection in the United States<sup>1</sup>. When they do, store shelves will be filled with cheaper generic versions, and \$36 billion in profits will plummet right off the well-publicized patent cliff<sup>2</sup>. By 2014, the sales revenues of drugs having patents that will expire are just shy of \$90 billion<sup>3</sup>.

The next five years will see drugs representing about \$142 billion in current sales lose patent protection. This trend will only accelerate considering that the real growth areas for pharma in the coming years will be emerging markets.

The necessary shift in strategy will yield a slew of new entrants from big pharma that are not aimed at the masses for common medical conditions such as high cholesterol, but are instead targeted towards specific maladies. This will move the focus away from competition with generics, while at the same time addressing a market (and human health) need that has remained largely unmet.

#### New paradigm, new approach

However, fewer patents mean smaller markets and thus lower profits. M&A will continue to be a lynchpin for both big pharma and the middle market, but the way in which companies come together must be geared to produce ultimate profitability.

There is already momentum gathering that demonstrates the emphasis on strategic buys that fit the new paradigm. Before the Sanofi-Genzyme merger was announced, activity

was clearly on the upswing across the market; while still not back up to the pre-recession levels, M&A in the sector rose sharply in 2010 with 2011 poised to show even further growth<sup>4</sup>.

Amidst this activity, the shift in targets is clear. Last year saw 91 acquisitions of biotech firms with market capitalizations exceeding \$100 million<sup>5</sup>. With an extended regulatory process, companies that are struggling today but who are in a position to grow with the economy may find suitors at the door.

There is no doubt, then, that Big Pharma is looking to buy, but only if the price is right. Given the choice, companies will buy back stock before they overpay for a small acquisition.

In that light, due diligence and pre-close planning have taken on magnified roles, and pharma must focus on extracting the most value possible out of each transaction. Beyond the pipeline, leaders should be examining opportunities to improve infrastructure, supply chain, compliance, and other critical areas in an effort to create a post-merger entity that achieves all of its stated goals.

Transaction planning should be considered through a lens of five specific stages:

- **Target Identification and Planning** Today acquirers must assess specific industries, identify opportunities, and evaluate the strategic viability and potential value of target companies.
- **Operational Due Diligence and Integration Requirements** Conducting financial and comparative analyses, documenting and quantifying operational improvement opportunities, obtaining a firm grasp on a target's value drivers, and developing a roadmap to a successful integration are the keys to game-changing improvements.
- **Pre-close Integration Planning** Pre-close both sides must fully explore the integration requirements, including the development of Day 1 implementation plan, synergy validation and capture, and decision-making protocols. The time and resources expended before closing should be focused on making sure that both sides are prepared to hit the ground running.



• **Day 1 Integration and Synergy Capture** Newly merged entities must be up and running on Day 1, with a focus on critical items such as 100-Day Plan, post merger integration (PMI), synergy capture, key performance metrics, new organization implementation and change management.

• **Operational Excellence** Every area of the organization - management teams, R&D, manufacturing, compliance, and marketing - are critical to building an operating model that is geared towards sustainable results and long-term competitive advantage. Leaders should avoid the common 'top down' approach, which relies on directives from the executive suite to facilitate change. On the contrary, it is crucial to establish clear lines of communications and bring the full enterprise together around clear lines of ownership and accountability.

In the field, this approach has historically resulted in a near flawless Day 1, the capture of a minimum of 40% of synergies within the first 100 days, a 25-30% reduction in the integration period, the identifying and capturing of 1.5 - 2X typical synergies, and the retaining of critical talent, customers and revenue. With companies running inevitably towards the patent cliff, executives should be seeking strategies to ensure momentum stays on their side.

Labs around the world are collaborating with external partners and using next generation sequencing technologies to speed up the road to approval, or to fail faster and cheaper. Even with outside help and new techniques, companies will not be in a position to bring new drugs to market fast enough to make up the profits that will be eaten by generics.

Acquisitions will increasingly be the answer. Promising new areas uncovered by M&A may help buyers gain greater profitability, but if the integration is not planned and executed properly, the merger will likely fall short of its full potential. ■

1 Are we living in the end of the blockbuster drug era? Drug News & Perspectives, B. Debnath, L.Q. Al-Mawsawi, and N. Neamati, December 23, 2010. 2 Big Pharma Patent Expirations To Sock 2012 US Drug Sales, Dow Jones, Peter Loftus, February 15, 2011. 3 Big Pharma Is One Big Graveyard for Stocks (2/17/11), Seeking Alpha, Jim Cramer, February 17, 2011. 4 The Myth of the 'Patent Cliff', Xconomy, Stewart Lyman, November 29, 2010. 5 Pharma M&A activity gains momentum, Bizmology, Anne Law, January 19th, 2011. 6 How Big Pharma Will Survive the Patent Cliff, Minyanville, Lisa LaMotta, April 21, 2010.