

* Pharma FORECAST

SIMON KING, a pharmaceutical company analyst at Datamonitor, comments on trends expected to impact “big pharma” in 2011.



Simon King

➔ **PV:** *Despite a challenging year for Roche, you say restructuring will help the company maintain a strong fiscal position. What other factors do you think will have a positive impact on the company?*

KING: One of the key factors that will drive sustained sales growth for Roche over the 2009 to 2015 period is the company's lack of exposure to patent expiry and subsequent small-molecule generic sales erosion. Just two products, CellCept and Boniva/Bonviva, are expected to suffer significant generic sales erosion upon expiry. Roche also generates a high proportion of revenue from its monoclonal antibody (MAB) portfolio — with more than half of total revenue derived from this technology type.

In contrast, exposure to generic competition — as exemplified by the patent cliff that is expected to impact the industry from 2010 to 2012 — will act as the main barrier to sales growth across the rest of the big pharma peer set.

Furthermore, and away from the company's prescription pharmaceutical business, Roche's diagnostic division will continue to play a key role in the group's robust financial outlook. Roche operates a 'twin-pillared' structure comprising its prescription

pharmaceutical and diagnostic divisions. As a result, the company is well-positioned to exploit related sub-markets, from predisposition testing and prevention to diagnosis, therapy, and treatment monitoring. This business model is unique within the pharmaceutical industry and allows Roche to take maximum advantage of synergies between its pharmaceutical and diagnostics divisions.

➔ **PV:** *How will Merck's new CEO Kenneth Frazier impact the company's strategic direction in 2011?*

KING: It's difficult to gauge the impact of a new CEO, but Mr. Frazier has certainly been positioned at the center of key strategies that will continue to be integral to the commercial outlook of Merck, including a global sales model, expansion into emerging markets, and an improved cost structure.

➔ **PV:** *Do you think CEO Joe Jimenez's goal of moving Novartis toward specialty drugs is characteristic of how other big pharma companies will position themselves?*

KING: Big pharma players have been diversifying into specialty drugs and away from primary-care or mass-market medications for some time. Roche has been the leader of this strategy via its movement into the market for monoclonal antibody cancer products, which was driven primarily via its relationship with Genentech.

I would argue that Novartis has been implementing such a strategy for some time before the appointment of Joe Jimenez, who has effectively been re-iterating a long-standing strategy in recent months. Products such as Gleevec/Glivec are a clear demonstration of this and, of note, the company is implementing a much broader diversification strategy, including its investments in the areas of vaccines, generics and, via Alcon, ophthalmology products.

Sanofi-Aventis' increasing diversified business model is reaping rewards as growth across consumer, generic, and vaccine divisions has helped to compensate for generic competition within the branded pharmaceutical segment. Generic erosion continues to impact performance, driven in part by the somewhat unexpected approval of a generic Lovenox product. With Plavix sales also in decline due to loss of European patent exclusivity, Sanofi-Aventis' anti-thrombotic empire is in collapse.

AstraZeneca has not followed many of its peers in diversifying into lower margin but more stable segments, and its 'pure play' pharma model is becoming questionable in light of intensifying generic competition — Arimidex, Pulmicort Respules, and Toprol-XL being the key casualties. Exposure to generics is also evident at the geographic level with a sharp decline in U.S. sales, thereby increasing the importance of AstraZeneca's planned expansion in emerging markets.

Crestor and Symbicort remain the jewels in the crown — sales up 20% and 19%, respectively — but the question remains as to how Crestor will perform beyond late 2011 when generic Lipitor becomes available.

As a result, AstraZeneca's growth outlook will remain heavily tied to new product launches and the progression of late-stage products through the regulatory arena. Sentiment moving into 2011 will, therefore, be significantly shaped by the FDA's decision on Brilinta, which was expected in December. AstraZeneca cannot suffer any further late-stage setbacks.

➔ **PV:** *U.S. healthcare reform is expected to impact all companies, and David Brennan, CEO of AstraZeneca, recently said reform would lower his company's results by \$300 million this year and about \$600 million next year. Is there any upside for the industry in terms of healthcare reform despite the significant dollar impact?*

KING: Datamonitor's broad view on the impact of healthcare reform is a neutral one: companies will suffer short-term hits due to increased rebates but in a few years are likely to see the benefit of increased sales tied to an increase in the number of U.S. citizens with healthcare insurance. Furthermore, as chairman of PhRMA, David Brennan has been an advocate for U.S. healthcare reform and is still positive about it, only saying it needs a 'few tweaks.'

➔ **PV:** *What do you believe are the top three pressing issues big pharmaceutical companies will face in 2011, and why?*

KING. No. 1 — Patent expiries; 2011 will be the nadir of the patent cliff. Pfizer will suffer the most significant hit due to Lipitor losing U.S. exclusivity in November 2011.

No. 2 — The continued emergence of the biosimilar market. With EU legislation emerging late in 2010, the generic Lovenox approval in the United States and more developments over next 12 months will spur on development of this market.

No. 3 — Companies need to seek to dilute shareholder pressure and avoid knee-jerk reactions to big patent expiry hits, while forced large-scale M&A activity threatens ongoing diversification strategies. **PV**

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