

## The vaccine industry – still growing, but more slowly

**LONDON, UK----11<sup>th</sup> February 2009----ExpertREACT.** All of the major vaccine companies have reported their full year sales for 2008. Analysis indicates that when comparing on reported basis, the Top 5 players sold \$17.5 billion worth of vaccines in 2008, a 5-7% increase on 2007. This growth rate is slower than 2007 over 2006 partly due to continued maturation of the blockbuster Gardasil and lower growth in flu vaccine sales

Currently the Top 5 vaccine players are considered GSK Biologicals, Sanofi Pasteur, Merck & Co, Wyeth and Novartis Vaccines. In addition, Sanofi Pasteur and Merck & Co have a joint venture company (SPMSD) which encompasses sales in a number of European (EU) countries which are not consolidated by the parent company Sanofi Aventis. Analysis of recent reported company results indicates that the Top 5 players sold around \$17.5 billion worth of vaccines in 2008. The top selling products for 2008 were the human papilloma virus (quadrivalent HPV) vaccine which recorded \$1.4 billion, a 5% decline on 2007, and Wyeth's *pneumococcal* vaccine, Prevnar (PCV-7) which recorded an increase of 8-10% (\$2.7 bn worldwide sales). Subject to shareholder approval Wyeth vaccines is expected to become part of an enlarged Pfizer group later this year.

In terms of company and overall industry performance, full year results for 2008 show different dynamics from those observed this time last year. This is mainly due to a large impact of currency fluctuations i.e. an appreciating US dollar and a number of newer vaccines reaching different parts of their launch lifecycle. On a reported basis **VacZine Analytics** calculates that the industry grew 5-7% over 2007, which is much lower than the ~40% 2007 growth over 2006. On a comparable basis i.e. recalculating 2007 year-end sales with exchange rates used for 2008 year-end, the year-on-year growth rate of the industry appears higher at around 20%. Exchange rate fluctuations are especially relevant to GSK and Sanofi Pasteur which sell a significant proportion of their products in the US market but report in British Sterling and Euros respectively.

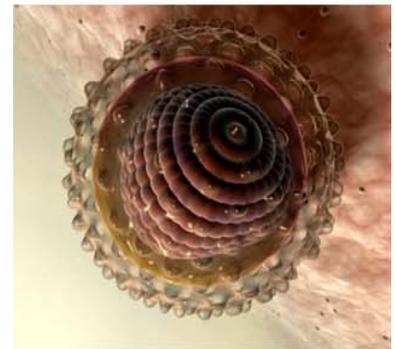
As a single reporting entity, GSK Biologicals now reports the highest number of dollar sales (\$4,697m) of the top players experiencing double-digit growth (~18%) on 2007. Main drivers are the increasing uptake of Rotarix (rotavirus) and Cervarix (bivalent HPV vaccines). GSK's adjuvant containing Cervarix, which is still awaiting US FDA approval, surprisingly recorded \$231m in sales, and a significant increase on the \$18 m recorded in 2007. According to GSK senior management at a recent analyst event (1), Cervarix commands "80% of the available volume in the largest EU tenders", namely the UK and Netherlands. However, on a value basis, SPMSD's Gardasil also recorded full year net sales of E584 million. In other areas GSK's core pediatric and hepatitis franchise's continued stable growth. Interestingly, GSK senior management recently confirmed that the pending Synflorix (*pneumococcal* vaccine) "may not be a US product".

When comparing 2007 to 2006, US Merck & Co previously reported an explosive growth of full year sales (>100%) on a reported basis mainly due to the US ACIP approval and subsequent rapid launch of Gardasil. Indeed the company states that Gardasil cumulative end market revenue since launch amounts to ~\$4 billion with >36 million doses sold through September 2008 (Merck Figures). However, in their recent corporate earnings release Merck & Co did not directly state their full year global vaccine sales which are calculated to be in the order of \$4,151m a slight decline on 2007. Although the company observed strong growth in its ZOSTAVAX and ROTATEQ products, there were reported declines in its other viral vaccines VARIVAX, M-M-R II and PROQUAD (\$1.3 billion total sales for 2008) (2).

Sanofi Pasteur as part of their 2008 full year results and outlook (3) state they are the world's leading vaccine company with a 21.8% share if they include 50% of SPMSD joint venture sales (E1,272 million, 2007 total). However, according to the same company calculations Merck & Co and GSK also have ~21% shares making such a claim subject to marginal differences in sales calculation methodologies. Of most note is the company's strong growth in pediatric vaccines (+21.9%) driven mainly by the US launch of Pentacel, a combination pediatric vaccine. Although other product/franchises such as Adacel and Menactra experienced growth, other important franchises such as flu (seasonal + pandemic) experienced sales declines on a comparable basis. In terms of the new product development pipeline Sanofi state they have initiated the development (CAPEX) of a multimillion dollar production facility for their new dengue vaccine, currently in Phase II suggesting some confidence in the product's future.

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Also, for H2 2009, Sanofi also expects to file regulatory submissions for their Japanese Encephalitis vaccine, IMOJEV™ in Asia and importantly, the infant/toddler (9-12 months) US submission of Menactra (meningococcal ACWY vaccine). IMOJEV™, a one-shot live product may eventually compete with Novartis Vaccines IXIARO™ which recently won first approval from the Australian regulators (TGA).

Novartis also reported sales growth of their Vaccines and Diagnostics division (acquired from Chiron) with 21% sales growth over 2007 (4). Like Sanofi, the company also experienced lower sales of their US influenza seasonal vaccines (Fluvirin) but states this was offset mainly by growth in diagnostics and a one-time revenue recognition of \$50 million from a contract renegotiation with a customer that uses NVS produced components to produce pediatric vaccines. Novartis's lead development vaccine, Menveo™ (meningococcal ACWY vaccine), which had been previously submitted last year for EU/US use in 11-55 yrs is to be delayed for the infant indication and now is expected to be submitted in 2011 upon FDA request for more data (1500 infants). It is likely Sanofi's Menactra will have first-mover advantage in the US infant market although NVS is aiming for vaccination beginning 2 months of age.

Looking at sales growth analysis of recent years it is clear that lifecycle effects of a single blockbuster vaccine can have a significant impact on the whole industry. This has especially been the case with Prevnar (PCV7), and then Gardasil which effectively defined new additional market segments. Whether the next round of "blockbuster like" products achieves this same effect is debatable as these candidates (PCV-13, Synflorix and Menveo) will to some degree switch existing customers on the basis of certain enhancements. Clearly, in the mid-term new industry growth will be derived from totally novel additions possibly, meningococcus B or indeed, dengue and *Staphylococcus aureus*, all currently in Phase II testing.

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VacZine Analytics is a new strategic research agency based in the United Kingdom. Its aim is to provide disease and commercial analysis for the vaccine industry and help build the case for developing new vaccines.

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