

The vaccine industry in 2009 – well past the \$20 billion barrier

LONDON, UK----18th February 2010----ExpertREACT. Now that all of the major vaccine manufacturers* have reported their full year 2009 results it is that customary time to analyze the industry in terms of current sales value and discuss future potential/competitive dynamics. **VacZine Analytics** reviews the current situation.

According to our calculations, we estimate that the Top 5 vaccine companies sold around \$20.7 bn of vaccines in 2009, which in non-comparable terms was ~10% increase on 2008. On a comparable basis i.e. recalculating 2008 year-end sales with current exchange rates, the rate of growth is higher at around ~17%. Considering that the Top 5 companies account for around 85% of industry sales, and other companies such as Medimmune (AstraZeneca), Baxter and CSL Ltd have recorded significant “new” revenue due to H1N1 vaccine orders, it is reasonable to suggest that the global vaccine industry, including the contribution of various local producers, may be even approaching the \$25 billion mark. Indeed, most major companies forecast even higher market estimates for later years, for example, Sanofi Pasteur recently estimated the global vaccine market to reach €23 bn in 2013 (1).

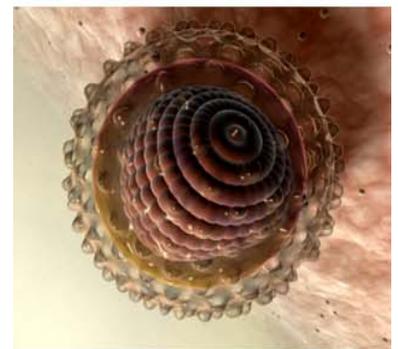
It is of little surprise that the H1N1 pandemic, which emerged last April, has greatly contributed to the fortunes of the major players, especially GSK, Novartis Vaccines and Sanofi Pasteur which collectively shipped around 320 million doses of monovalent vaccine to the end of 2009. Along with contributions from Medimmune, Baxter and CSL, **VacZine Analytics** estimates an additional ~\$3.6bn in revenue was added to 2009 year-end sales of which GSK Biologicals benefited the most followed by Novartis. The additional contribution of H1N1 vaccine sales to overall industry value was slightly offset by declines in the revenues of Merck & Co who recorded \$3632m in 2009 sales as compared to \$4206m in 2008. Significantly, both GSK and Sanofi Pasteur have also stated that they expect H1N1 revenues to be similar and “significant” in 2010. This coupled with expected product launches in *meningococcal* ACWY vaccines e.g. Menhibrix, Menveo, and Menactra suggests that industry growth is set to continue in the near term.

We calculate that Novartis Vaccines (excl diagnostics) experienced the fastest company growth in 2009 over 2008 in terms of vaccine sales (+53%). This was due to the additional \$1bn of net sales the company booked in Q4 2009 which greatly improved the division’s operating income. Among many other government contracts, Novartis Vaccines previously won \$978m in US HHS contracts for 90m doses of H1N1 coupled with provision of its oil-in-water based adjuvant MF-59, which curiously is still not approved for seasonal flu in the US. Similar to GSK, Novartis lowered the amount of seasonal flu (Fluvirin) doses it supplied to the US market from the typical 40 million to 27 million most likely due to limits on operational capacity. Only Sanofi Pasteur managed to ship an increased amount of seasonal US doses (50m) on the previous season although surprisingly, their H1N1 revenues were the lowest (~\$600m) of the major suppliers.

In 2009, many major companies notably stated their intentions and indeed, sales performance in emerging markets or often denoted, “BRIC” or “ROW” regions. GSK and Sanofi Pasteur now conduct a significant amount of their business in the region with proportions of around 30% of total sales. Sanofi Pasteur, which experienced double digit growth in the region in 2009 (~16%), is expecting their “ROW” business to accelerate. This will especially be the case if the company successfully launches in the region its vaccine candidate to prevent dengue fever, currently in Phase IIb. In the nearer term, the company has also submitted for approval its one-dose vaccine to prevent Japanese Encephalitis (JEV) (IMOJEV™) in both Australia and Thailand. Sanofi Pasteur has also recently advanced a rotavirus vaccine candidate into the clinic via its Indian division, Shantha Biotechnics (2), although rivals Merck & Co and GSK are far ahead with licensed candidates.

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Pfizer (legacy Wyeth) now report their vaccines business within their Specialty care business unit. For PCV-7 (Prevnar) which sold around \$2.7 bn in 2008, the company reported two and half months of Wyeth's US operations and one and half months of the international operations totalling \$287m of sales. Although not stating the exact figure for PCV-7 it is likely the 2009 is very similar to 2008. Pfizer still openly states its high expectation for successor PCV-13 (*Streptococcus pneumoniae* vaccine) in adults >50 yrs which could add an additional >\$1.5bn to the total franchise beyond the indication in children. Looking to 2010, PCV-13 remains the most likely new revenue driver to the whole industry after further H1N1 vaccine sales.

Merck & Co, Pfizer's US rival, largely had a disappointing year mainly due to a 20% sales decline in its Gardasil HPV vaccine and ZOSTAVAX (-11%). The decline in Gardasil sales may be partly due to the end of selected catch-up campaigns in various markets but also due to continued penetration of GSK's Cervarix, now a \$300m product. Merck continues to attempt label extension of Gardasil recently releasing Phase III initial data indicating that the vaccine is efficacious against anal intraepithelial neoplasia (AIN) in men who have sex with men (4). On a positive note, Merck & Co's viral vaccines (VZV, MMR-II and PROQUAD) experienced a 13% increase in sales. Also, surprisingly the group reported Pneumovax (PPS-32) sales as a single product line at \$346m in 2009, which suggests the extent of *pneumococcal* vaccination outside the infant category is sizeable. No doubt Pfizer will observe this figure with interest.

*Top 5 vaccine companies only – GlaxoSmithKline Biologicals, Sanofi Pasteur, Merck & Co, Pfizer (legacy Wyeth), Novartis Vaccines (excl diagnostics).

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References and Notes:

- 1) Sanofi Aventis 2009 Full Year Results, 10th February 2010. Available at: http://en.sanofi-aventis.com/binaries/2010-02-10_Results2009_EN_tcm28-27180.pdf. Accessed February 2010
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- 3) Merck & Co. Full Year 2009 Results. Available at: <http://www.merck.com>. Accessed February 2010.
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