

Vaccine major players – Q2 2010 round up of results and R&D

LONDON, UK----6th May 2010----ExpertREACT. The Top 5 vaccine companies have now announced their Q2 sales which were approximately \$2bn less than Q1 mostly due to declining H1N1 vaccine sales. In underlying business, the battle intensifies in *meningococcal* and *pneumococcal* vaccines, and preparations for a predicted record US influenza season.

According to our analysis, the vaccine major players* sold around \$4.62 bn worth of vaccines in Q2 2010, a decline on our calculated figure for Q1 of this year (\$6.34 bn) (1). Most of the decline can be attributed to slowing H1N1 pandemic vaccine sales which still amounted to \$708m, but a big reduction on the Q1 figure of \$2.83 bn. Stripping out H1N1 sales, Q2 of this year is similar on a reported basis to Q2 of 2009.

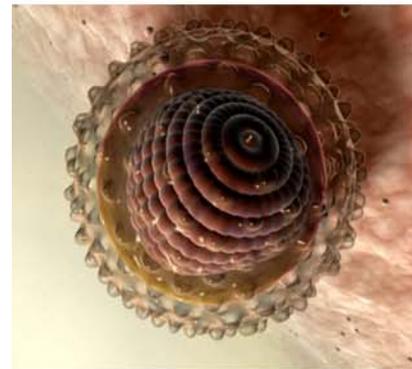
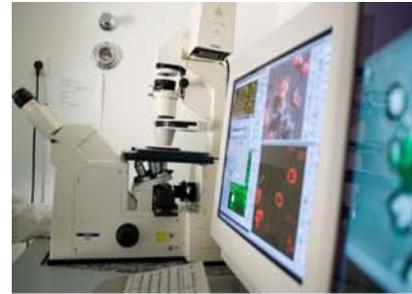
In reported dollar terms, GSK were again the leading company in Q2 selling approximately \$1.395 bn (£664m) of vaccines (2). In its results presentation the company gave an update on new product launches keen to emphasize that these were driving most of its revenue growth across all divisions. For vaccines, Cervarix (bivalent HPV vaccine) recorded \$194m so far in 2010 being launched in Japan and now US; although for the latter GSK stated sales were only \$8m due to a delay in VFC (Vaccines For Children) funding. Once this funding stream comes on line there should be significant upside possibly driving Cervarix to a half billion dollar/yr product. In 2009, Cervarix sold \$292m. For GSK's 10-valent pneumococcal vaccine Synflorix, the company sold \$127m so far in 2010 stating the product had gained sizeable market shares by volume in key countries such as Germany (~20% share), Turkey and Hong Kong (~70%). However, looking at value – it appears that GSK's strategy is to get "a foot in the door" over Prevnar/Prevenar with low pricing. Lastly, GSK still sold \$400m worth of H1N1 in Q2 2010 bringing its total so far since 2009 at \$3.5bn. Clearly GSK's large scale reentry into the flu business back in 2004 was a sound move because this infrastructure building allowed the company to later capitalize on the H1N1 pandemic.

Sanofi Pasteur moved into second place in dollar terms for Q2 2010 with reported sales of ~\$1,095m (€748m) (3). Pediatric vaccines made up the highest proportion of sales (~37%) with the company reporting improved performance on the previous quarter for Pentaxim (+33.3%) and Pentacel (+8.0%). Sanofi, which did not fare the best from the H1N1 pandemic, remains heavily focused on seasonal flu and expects "record" demand in the US. This will be driven by new ACIP recommendations which recommend vaccination for everyone >6 mos (4). In the same document, the committee for the first time include, Fluzone® high dose IM, a product for >65 yrs containing 60mcg of influenza antigens rather than the standard 15 mcg. Other notable elements of Sanofi's drive to control seasonal influenza include a new quadrivalent seasonal flu vaccine in Phase II and an expected regulatory decision on Fluzone® ID in the US, a microinjection product already approved in the EU. **VacZine Analytics** has assessed the commercial potential of Sanofi's other significant universal influenza (M2e) program in other analyses (5, 6).

Novartis Vaccines and Diagnostics (NVS) sold \$564m in Q2 2010, a steep decline on the Q1 figure of \$1,361m (7). Once again this was due to decreased revenues being booked from H1N1 sales. For influenza, NVS still sold \$200m of H1N1 vaccines and already has announced its intention to supply 40 million doses of Fluvirin to the US seasonal market. However, the company now appears focused on promoting its two next significant revenue streams from new meningitis vaccines (ACWY and B). According to the company, Menveo (MenACWY-CRM), is now recording its first US sales although (to our knowledge) the company has not specifically stated a sales figure. Interestingly, incumbent Sanofi Pasteur state that Menactra sales were "only down 3% (versus the previous quarter) despite a new competitor" (3) suggesting they believe Menveo initial sales were low. However, Menactra itself is down 13.1% on H1 2010 due to a "declining" catch-up cohort indicating that the underlying market is contracting. Both NVS and Sanofi, along with GSK are pursuing infant vaccination with ACWY to enlarge the market although this is meeting hesitancy at the US ACIP committee.

Novartis' development of a meningitis B vaccine received various mentions in its Q2 2010 results. The company reiterated that the global market "is large at \$1.1bn and growing, expected to reach \$2.7bn by 2016". Assuming the company is referring to all meningitis vaccines and the additional revenues attributable to new B and ACWY vaccines in 2016, these figures sound conservative. For its serogroup B vaccine program, NVS states it is on track to file in the EU at the end of 2010 and is continuing discussions with the FDA regarding the Phase III trial; the same position stated in its Q1 results. This quarter, NVS released a slide within its results presentation indicating that EU incidence of meningococcal B disease in infants (<1 year of age)/100,000 population were 5 to 15 times the US figure (7). One could speculate that this, coupled with conservative market estimates, suggest that NVS believe a serogroup B vaccine would be more of a EU product. This is a possibility; however, personal communications to **VacZine Analytics** suggest the US ACIP could be also interested in a *meningococcal* B vaccine for US infants, which still exerts a higher proportion of cases than ACWY. Furthermore, similar to MenACWY the adolescent cohort remains an additional vaccination segment for a serogroup B vaccine.

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For the first time Pfizer (formerly Wyeth), which reports its vaccines business within the Specialty Care Unit, gave actual sales to its full Prevnar/Prevenar franchise which recorded \$900m for Q2 2010 alone and \$1706m for the first half of the year (8). For the first half PCV-7 recorded \$851m and PCV-13 recorded \$851m. Interestingly, sales of PCV-13 exceed PCV-7 when reported for Q2 alone (\$569m to \$331m) suggesting the switch to the higher coverage product is proceeding successfully. Most of the switch appears to be occurring in the key US market where PCV-13 was outselling PCV-7 approximately 3 fold in Q1 and then 14 fold in Q2. Upon closer inspection of the regional Q2 figures PCV-7 is still the most dominant product outside of the US, although “developed Europe”, as one would expect, is further ahead on the switch. Emerging markets sold only \$15m for PCV-13 which surprisingly is the same amount for GSK’s Synflorix (10-valent) in the ROW region. Pfizer is also pursuing a meningococcal B vaccine.

Lastly, Merck & Co reported its Q2 2010 figures indicating a decline of Gardasil (HPV vaccine) US sales (\$219m) on the previous quarter and a similar period in 2009 (9). For Gardasil, the company did state that the CHMP issued a positive opinion to extend the vaccine indication to included women up to age of 45 years, although in the US coverage in older women appears quite low. Back in June, Vienna based Intercell AG partnered with Merck & Co, mentioned that the developmental vaccine for *Staphylococcus aureus* (V710) would be delayed due to slower than expected event rate in the current trial. This is a temporary setback although the vaccine, if successfully developed, is the next big blockbuster for Merck & Co.

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***Top 5 companies:** GSK Biologicals, Sanofi Pasteur, Merck & Co, Pfizer (Wyeth) and Novartis Vaccines and Diagnostics.

References and Notes:

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- 4) Prevention and Control of influenza with vaccines. Recommendations of the Advisory Committee of Immunization Practices (ACIP) 2010. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr59e0729a1.htm?s_cid=rr59e0729a1_e. Accessed August 2010
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