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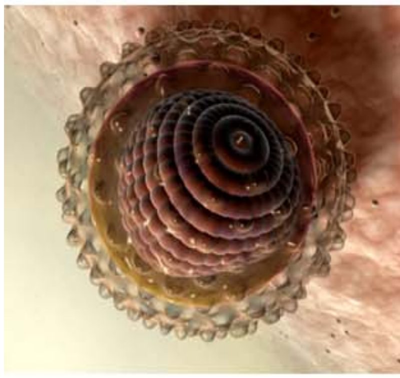
# Vaccine major players – Q3 2010 round up of results and R&D

**LONDON, UK----2nd November 2010----ExpertREACT.** The Top 5 vaccine companies have now announced their Q3 sales which are estimated to total ~$5.7bn, an increase on Q2 and the same period last year. Seasonal influenza vaccines are strong revenue contributors for suppliers to a predicted record US season with good evidence that effective life-cycle management is possible.

According to our analysis in Q3 2010, the vaccine major players* sold around $5.7 bn worth of vaccines which is an increase on the $4.6bn figure calculated for Q2 **(1)** and the same time last year. Characteristically the large influenza vaccine suppliers Sanofi Pasteur, GSK Biologicals and Novartis Vaccines at this time of the year book revenues for doses shipped in advance of the important US influenza season, which this year is expected to be a record. For this quarter it is estimated that around ~$1.2bn in seasonal influenza sales have already been registered based on reported sales and/or doses supplied.



GSK Biologicals sold $1.5bn (£982m) of vaccines in Q3 2010 reporting strong growth in USA (+32%), Emerging markets (+29%) and Asia Pacific/Japan (>100%) **(2).** Highlights were a sharp increase in Synflorix sales, the company's 10-valent *pneumococcal* vaccine, which recorded £90m in Q3, more than the H1 2010 figure of £83m. In a previous investor presentation **(3)**, GSK stated that Synflorix was now approved in 71 countries and had reached several notable milestones, one of which, the long-term contract with the Brazilian government, had boosted Q3 revenues. GSK's bivalent HPV vaccine, Cervarix also grew 64% in Q3 registering £48m, £19m of which was due to Japanese sales. GSK state that over half of competitive tenders are won by Cervarix (two thirds by volume) which should be on track to beat 2009 sales of £187m.

GSK is keen to look beyond the temporary suspension of Rotarix (rotavirus vaccine) sales due to the PCV-1 (porcine circovirus-1) contamination story reported earlier this year, although sales were down 40% in Q3. The development of PCV-1 free vaccine is stated to be ongoing **(3).** In terms of late stage R&D vaccines, GSK halted development of its Herpes vaccine, Simplirix in late September due to results of the ongoing Herpevac trial conducted with the US National Institute of Allergy and Infectious Diseases (NIAID) since 2002. Simplirix had shown some efficacy in double HSV seronegative women in a previous Phase III trial but in the latest trial showed no efficacy against its primary endpoint to prevent HSV mediated disease **(4).**

Sanofi Pasteur sold ~€1.2bn of vaccines in Q3 2010, a similar level to GSK on dollar terms. The company, which back in July stated it was planning to deliver a record 70 million doses of flu vaccine to US providers **(5)**, was boosted by seasonal influenza vaccine sales of €480m. Interestingly of these, Sanofi reported €41m sales of Fluzone High Dose IM (60mcg per strain haemagluttinin) in the US elderly segment which equates to a sizeable ~10% of total seasonal vaccine sales. At this early stage, it would appear that Fluzone High Dose IM could become a case study of how to successfully life-cycle manage and differentiate within the "crowded" and commoditized influenza vaccine market. Similarly, it will be interesting to observe the penetration of Sanofi's Intradermal flu vaccine (INTANZA/ID FLU) in various markets including Canada (announced mid-September) 2010 **(6)** and US (BLA filed) **(7).** Other Q3 highlights for Sanofi were strong performances of Adage in the US and rabies vaccines in the travel and other endemic vaccines category. Sanofi also made an acquisition in later September of US-based VaxDesign to bolster its ability to predict human immune responses to new antigens **(8).**

Novartis Vaccines and Diagnostics (NVS) sold $632m of vaccines in Q3 2010 **(9)**, a figure increased 21% over Q2. This quarter the company gave little granularity to its figures, at least at the product/individual franchise level. NVS stated they were able to ship around ~35 million doses of seasonal vaccine to US customers, an increase of 40% last year but less than the 40 million predicted in July. This comparison is of little value since the company was actively focused on seperate H1N1 monovalent vaccines at the time. This year H1N1 is included in the seasonal vaccine according to WHO recommendations. Again, similar to last quarter NVS mentioned first sales of Menveo (quadrivalent *meningococcal* ACWY vaccine) contributing to performance although exact figures were not indicated. Menveo sales should be supported by updating of US ACIP recommendations to include a booster doses of *meningococcal* vaccine 5 years after the first dose (if given at 11-13 yrs).

Another potential boost to NVS is a report from strategic alliance partner Vienna-based Intercell AG that their Phase II *Pseudomonas aeruginosa* (IC-43) vaccine was able to show an indication towards reduced mortality in ventilated ICU-patients (n=400) **(10).** As long-term proponents of the field, **VacZine Analytics** believes the data; gives nosocomial (hospital) vaccines a much needed boost supporting the concept that certain patient groups can indeed be targets for preventative vaccination. NVS has certain options to IC-43 and are believed to be currently in discussion regarding next steps. Intercell are also to report Q3 sales on November 9th which will indicate how sales of Ixiaro, Japanese encephalitis vaccine (commercialized by NVS) are progressing.

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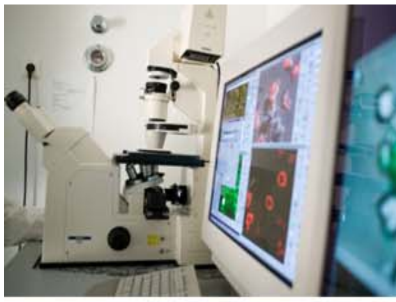

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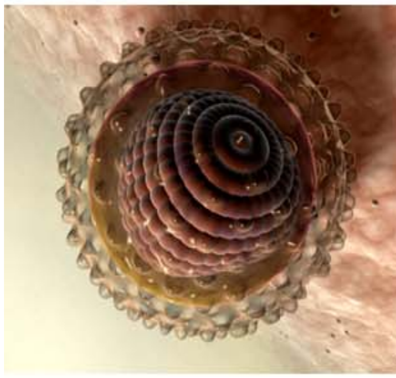
Merck & Co who reported sales of $846m and $832m in Quarters 1 and 2 respectively, are estimated to have increased sales for Q3, mainly as a consequence of its other viral vaccines, which include VARIVAX, MMR-II and PROQUAD which recorded $434m (a ~27% increase on Q2) but down 6% on the year earlier **(11).** Through Rotateq (rotavirus vaccine), the company has also been involved with authorities regarding the PCV-1 contamination although sales do not appear to have been affected in percentage terms as much as GSK ($119m, Q3). In R&D, Merck & Co who play a "less is more" strategy are advancing a conjugated *Streptococcus pneumoniae* vaccine (V114) (reported 15-valent, identifier NCT01215188) suggesting the company is thinking beyond Prevnar-13 and planning to leverage off their expertise gained from Pneumovax (PPSV-23). In Q3, the Prevnar franchise itself reported $179m for PCV-7 and $735m for PCV-13 according to Pfizer's latest results: totalling ~$2.5bn so far for the year **(12)**. With revenues this high, new *Streptococcus pneumoniae* vaccines are still the most attractive market segment to aim for.





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

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