

2012 FY results – a flat industry poised for further growth

LONDON, UK----18th February 2013----ExpertREACT. In non comparable dollar terms the vaccine industry* barely grew in 2012 over 2011. However, with the EU approval of Novartis Vaccines' *meningococcal* serogroup b vaccine things could be set for change.

According to our calculations, the top 5 vaccine players* reported around \$21.4bn worth of vaccines in 2012 compared to nearly \$20.8bn in 2011. The figures, which are in non-comparable terms i.e using different exchange rates for each year suggest the industry experienced modest (~3%) in 2012. Because GSK reports in GBP Sterling and Sanofi Pasteur in Euros calculations between different analysts are subject to variation depending on methodology chosen.

Around this time last year we put forward the view that the vaccine industry was “waiting for its next burst of growth” (1). A year later one of the cited potential growth drivers i.e. Novartis Vaccines' *meningococcal* serogroup b vaccine has now received EU approval (2) and set to add significantly to industry yearly revenues over the coming years. This **ExpertREACT** article will briefly cover each company individually to see how they fared in 2011 and key anticipated events for 2012.

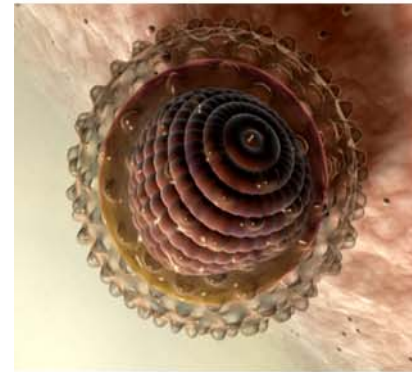
In dollar terms, GSK Biologicals again sold the most out of the major players in 2012 with \$5.2bn revenues (3) but sales had declined 2% on 2011. The main reason for the decline was the completion of a HPV vaccine “catch-up” program in Japan which declined Cervarix sales by 46% to £270m. Growth in other vaccine segments was evident with Infanrix/Pediarix, Rotarix and Synflorix growing 17%, 21% and 17% respectively. Other declines were experienced in influenza vaccines (-11%) due to a lower volume being supplied to the critical US market (21m versus 34m doses in 2011). Nimenrix®, a conjugate vaccine for invasive *meningococcal* disease caused by *Neisseria meningitidis* serogroups A, C, W -135 and Y, newly approved in June 2012 only registered £1m in EU sales in 2012. It is not yet available in the major US market. Quadrivalent Fluarix (QIV), again newly approved in December 2012 is expected to generate sales for the 2013/2014 season.

Sanofi Pasteur recorded €3,897m of vaccine sales in 2012 (4) an increase of 5.7% over 2011 at constant exchange rates. Annual sales increased faster in emerging markets (+9.1% CER) than mature markets (+4.1% CER). The company sold €384m of influenza vaccines in 2012, a slight decline on 2011 despite delivering 60m doses to the US market. Sales in emerging markets grew strongly (+55%, €65m). Sanofi is keen to promote its new differentiated portfolio of flu vaccines under the “right dose, right patient” motto (5) although it still remains to be seen whether this will pay off commercially. Sanofi experienced strong growth with its *meningococcal* A, C, W -135 and Y vaccine, Menactra which grew 94.6% in the fourth quarter due to good performance in Chile and Saudi Arabia. Full year sales grew to 21.8% to €564m.

In terms of vaccine R&D Sanofi is pressing forward with its dengue vaccine program despite the vaccine being previously shown to be efficacious only against 3 of the 4 dengue serotypes. The company is pursuing a large global phase III program with studies in LATAM and ASIA including 31,000 adolescents with results expected 2014. For its *Clostridium difficile* toxoid vaccine (ACAM-CDIFF) a multinational Phase III trial is planned to start in Q3 2013 after being granted a Fast Track designation by US CBER.

Novartis Vaccines and Diagnostics reported \$1858m sales for 2012 a decrease on the \$1996m recorded in 2011 (6). Novartis cited strong growth for Menveo its conjugate vaccine for invasive *meningococcal* disease (ACWY) at \$164m (+18% cc) in both the US and ROW regions. The loss making performance of Novartis V&D unit may be coming to an end with the *meningococcal* serogroup b vaccine, Bexsero™ which has now received EU approval. **VacZine Analytics** has previously forecasted this product could realise between 5 yr cumulative revenues of €1.47 bn (lo) to €5.46 bn (hi) between 2013-2017 dependent on various levels of country adoption (7). On an epidemiological basis countries such as Ireland, Ireland, New Zealand and the United Kingdom have high rates of serogroup B disease and would be expected to implement national immunization programs assuming funding is available in economically constrained times.

CONTINUED.....



CONTINUED.....

Similar to 2011, Merck & Co had a good 2012 with an impressive 35% increase in its lead product the quadrivalent vaccine Gardasil (8). Gardasil sold \$1.6bn in 2012 still supported by the new US indication for males. The company also cited strong public sector purchases as well as good performance in Japan and emerging markets for its lead HPV vaccine. Zostavax, Merck's shingles vaccine, sales in 2012 almost doubled on 2011 to reach \$651m mainly due to better supply and increased promotional efforts in the US. In recent investor presentations Merck & Co focuses on late stage vaccine R&D programs V212 (Herpes Zoster), V503 (HPV related cancers) and V419 a new pediatric hexavalent combination (9).

Lastly Pfizer's PCV-7/PCV-13 franchise registered \$4267m in 2012 a slight increase on the \$4145m recorded in 2011. It is still too early for the company's lifecycle management plan for its pneumococcal franchise to drive a further significant uptake in sales. In terms of R&D Pfizer gave some visibility of its R&D strategy under the motto "a Platform for all Ages and Geographies" (10). This covered the company's work in vaccines for *Staphylococcus aureus*, nicotine, *Clostridium difficile* and interestingly, IgE. Along with its program in meningococcus serogroup b, Pfizer's vaccine R&D has notably increased in prominence in recent years.

NOT FOR UNAUTHORIZED COPYING AND DISTRIBUTION

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

References and Notes:

- 1) VacZine Analytics. ExpertREACT: 24th February 2012. Available at: http://www.vaccine-analytics.com/ER_February_120224s.pdf. Accessed February 2013.
- 2) Novartis Vaccines Corporate Press Release. Jan 22nd 2013. Available at: http://www.novartisvaccines.com/newsroom/media-releases/2013/Novartis_media_release_Bexsero_EU_Approval_January_2013.pdf. Accessed February 2013
- 3) GSK Corporate Q4 Results Release. February 2013. Available at: <http://www.gsk.com/media/press-releases/2013/Results-announcement-for-the-fourth-quarter-2012.html>. Accessed February 2013.
- 4) Sanofi Pasteur. Annual Results 2012 – press release. February 2013. Available at: http://en.sanofi.com/Images/31846_20130207_2012RESULTS_en.pdf Accessed February 2013.
- 5) Sanofi Pasteur. Annual Results 2012. February 2013. Available at: http://en.sanofi.com/Images/31839_2013-02-07_Resutls_2012.pdf. Accessed February 2013.
- 6) Novartis Annual Results. Jan 23rd 2013. Available at: http://www.novartis.com/downloads/investors/financial-results/quarterly-results/q4-2012-media-release_en.pdf. Accessed February 2013
- 7) VacZine Analytics. MarketVIEW: meningococcus serogroup b vaccines (CAT No: VAMV031), updated Jan/Feb 2012. Available at: <http://www.vaccine-analytics.com/products-marketview/VAMV031.asp>. Accessed February 2013.
- 8) Merck & Co. Q4 2012 Earnings Conference Call. February 1st 2013. Available at: <http://www.merck.com/investors/financials/4Q12SERelease-01-02-2013.pdf>. Accessed February 2013
- 9) Merck & Co. Leerink Swann 2013 Healthcare conference. February 13th 2013. Available at: <http://www.merck.com/investors/home.html>. Accessed February 2013
- 10) Pfizer Presentation. UBS Global Healthcare conference. September 2012. Available at: http://www.pfizer.com/files/investors/presentations/public_ubs_092012.pdf Accessed February 2013

A printable version of this article is available upon request.

VacZine Analytics^(R) is a trading division of Assay Advantage Ltd, UK Company Number: 5807728

VacZine Analytics^(R) and "the spiral logo" are UK Registered Trademarks, 2009

© 2013 VacZine Analytics. All rights reserved.

