

# ExpertREACT™

VIEW ONLY

March 5th, 2015

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## 2014 FY Results – vaccine industry, still bumping along

**LONDON, UK----5<sup>th</sup> March 2015----ExpertREACT.** An ever-consolidating vaccine industry still reports yearly FY revenues within the \$20-22bn range. A new dengue vaccine (if approved) is more likely to change this than new serogroup b *meningococcal* vaccines. Sanofi Pasteur continues to perform a miracle value based transformation of its influenza vaccine franchise.

According to our analysis, the vaccine industry major players\* sold just over \$22 billion worth of vaccines in 2014. Taking into account exchange-rate movements, there does not seem to have been substantial growth in this figure for a few years. It is of note that in 2014, the British pound strengthened against the US dollar and the euro weakened affecting the sales of GSK Biologicals and Sanofi Pasteur, respectively.

British based **GSK** reported £3,192m worth of vaccines sales (1) stating that most of its regional business units experienced declines or flat performance. Notable growth spots were from Boostrix, which increased 16% to £317 million and Rotarix, which increased 7% to £376 million. Either competitive pressures or unfavourable phasing of government tenders relative to the previous year affected all other franchises. Lower production levels for 2014 adversely impacted Fluarix/Flulaval influenza vaccines, which saw a decline in sales by 8% to £78 million.

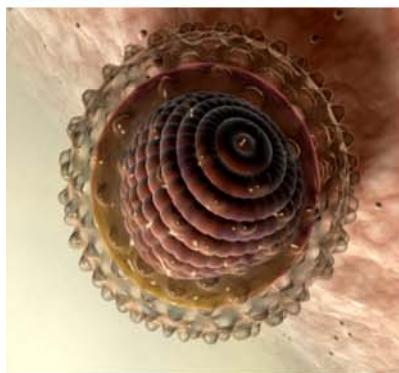
In early March, GSK reported that it closed its major three-part transaction with Novartis (2) of which a significant component involved vaccines, excluding influenza, separately sold to **BioCSL**. Documentation from the transaction revealed that the **Novartis** vaccines business, excluding influenza vaccines was approximately a \$950 million/yr concern with around 75% of turnover in the rest of world region. Information from the BioCSL acquisition also reveals that Novartis influenza vaccine business had net sales of \$527m to December 2013 (3). The documentation gives more transparency to the extent of losses of the Novartis business unit, hence the decision to divest from the Swiss corporate parent. GSK hopes that the acquisition of the Novartis business unit consolidates its leading position in vaccines, especially in the US market, although it still does not have a position in *pneumococcal* vaccines, varicella or Zoster (4). In mid February, GSK also announced that it acquired **GlycoVaxyn AG**, a specialist vaccine biopharmaceutical company based in Switzerland by purchasing the remaining shares it did not own for US \$190m (5). Acquisition of GlycoVaxyn AG allows GSK access to a range of novel programs directed towards the bacterial infections, notably shigellosis.

**Sanofi Pasteur** reported €3,974m worth of vaccines sales in 2014, an increase of 7.2% over the previous year (at constant exchange rates). Sales of influenza vaccines experienced significant growth (25%), driven by the US and Mexico (6). In the US, 64 million doses of influenza vaccine were sold, with the majority of sales (~88%) being derived from "differentiated" products which command significant price premiums over the standard Fluzone product; Fluzone HD is roughly 2 1/2 times more expensive (~\$25 per dose/private sector). The pediatric combination vaccine Pediacel, staged a good recovery after supply difficulties. Polio/Pertussis/Hib vaccines posted a 31% increase in US sales reaching €148m. Sanofi's Menactra appears to be fending off competition from the new Novartis competitor, Menveo. It reported 13.5% growth in the US market. For Sanofi all eyes await future revenue contributions from Sanofi new dengue vaccine, which has initiated submission in several endemic countries in Asia. The first license for this "first in class vaccine" is anticipated before year-end 2015 where 18m lyophilized doses are expected to be available.

**Merck & Co** reported approximately \$5.7 bn worth of vaccines sales in 2014 (7). The company stated that Zostavax (shingles vaccine) in Q4 2014 experienced its best quarter to date as a consequence of a direct to consumer campaign in the US, which increased sales by 7%. The product experienced growth in the international region (15%), which is expected to continue as part of a launch strategy into 25 additional markets globally. For Gardasil (HPV vaccine), although sales have experienced some declines due to catch up campaigns ending in various markets, the US ACIP committee in late February recommended the use of Gardasil-9 (9-valent) vaccine for routine use in males and females, 11 and 12 yrs of age. The use of the product in prior HPV vaccine recipients is to be discussed at a future ACIP meeting in June 2015. Gardasil recorded ~\$1,738 bn in FY 2014.

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\*excl SPMsD



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The new Gardasil-9 product is expected to cost around 10% more (8). Pneumovax, (PPSV23) also continues to be a growth product for Merck & Co recording \$746m in 2014, almost \$100m more than the previous year.

**Pfizer vaccines**, which recorded \$4480m in FY 2014 continues its transformation into a multiproduct business unit. Recently, the CDC ACIP voted to recommend TRUMENBA, its Serogroup B meningococcal vaccine for persons at increased risk (>10 yrs) (9). The vaccine was granted US accelerated approval in October 2014, and should now begin to recognise commercial sales, albeit modest. Despite a UK JCVI decision to use a new menB vaccine in infants, no program is still in place a year later due to prolonged negotiations regarding price.

Also in the EU, PCV-13 (Prevenar) gained an expanded indication for use in adults for the reduction of first episodes of community acquired pneumonia (CAP), including non-invasive/non-bacteremic CAP, and invasive pneumococcal disease (IPD) in adults aged 65 and older (10). Pfizer recognises great ex-US potential for PCV-13 driven by its continual efforts to expand indications for the vaccine. In R&D, Pfizer has provided recent updates for its, programs, focused on nosocomial bacterial infections. Notably, its *Clostridium difficile* vaccine candidate is currently on hold from its ongoing phase 2 study due to several observed cases of severe local reactogenicity. Both Sanofi Pasteur and Valneva AG are likely to be encouraged by this setback for Pfizer.

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