

H1N1 – boost to Novartis Vaccines, the industry but for how long?

LONDON, UK----28th January 2010----ExpertREACT. The recent results from Novartis AG group revealed that in 2009, H1N1 vaccine sales gave an extra \$1bn to the Vaccines & Diagnostics division. This much needed boost finally lifts the division into a respectable level of profitability but will also benefit other major flu players with better underlying businesses. **VacZine Analytics** discusses the issues and the biggest windfall in the industry yet.

Recently Novartis AG Pharmaceuticals reported their full year 2009 results (1). As a whole the group witnessed an 11% rise in net sales for 2009, totalling \$USD 44.3 billion with reported growth across all divisions. Significantly, Daniel Vasella, the group CEO for the last 14 years decided to “focus on strategic priorities” as Chairman and announced the appointment of Joe Jimenez as the new CEO effective, February 1st 2010.

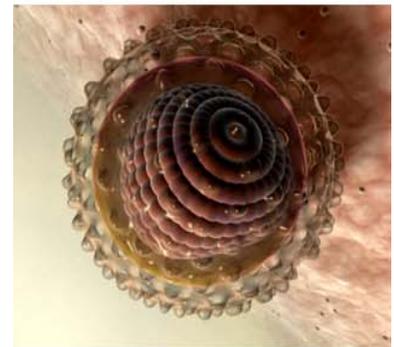
The latest group results were also significant for Novartis Vaccines and Diagnostics (formerly Chiron), which Novartis AG acquired in 2006 for ~\$5.1bn. V&D recorded full 2009 year sales of \$2,424m a 38% increase on \$1,759 m recorded in 2008. The large increase was due to an additional \$1 billion in sales of the H1N1 monovalent influenza vaccine directed to the global “swine flu” epidemic which emerged in April 2009. Novartis Vaccines state that they shipped around 100 million doses to governments around the world who decided to vaccinate vulnerable members of the population including pregnant women, healthcare workers and young children. Most significantly, the addition \$1 billion in H1N1 sales contributed to a sharp increase in operating income which rose from \$372m in 2010 from a meagre \$78m in 2008. This is welcome news because of many late stage programs e.g. Menveo (MenACWY-CRM), MenB and H1N1 render V&D a cost-intensive operation. Notably, V&D’s number of employees rose in 13% from 2008, now totalling 5416. The news also puts the return on net sales on V&D similar to other Novartis divisions such as Sandoz and consumer health, finally making the Chiron acquisition palatable.

Other companies which have supplied H1N1 vaccine are expected to report a surge in sales. GSK, who are due to report Q4 2009 on February 4th 2010, confirmed that approximately 130 million doses had been shipped in the fourth quarter which could be equivalent to £835m (\$1.3bn) in unaudited sales (2). The company also donated 60 million doses to the WHO. Sanofi Pasteur, a major producer of seasonal influenza stated in an investor seminar that they had received over 250m doses of H1N1 vaccine commitments for 2009-2010 (3). Based on the prices gained by other manufacturers it is likely that Sanofi Pasteur will gain around \$2-3 bn in sales although the contribution to 2009 results is dependent on the amount they shipped in Q4 2009. Sanofi’s results will be reported February 10th 2010. Lastly, CSL, Medimmune and Baxter Healthcare who supplied H1N1 vaccine in Europe (Celvapan) are also likely to witness a sales surge to their vaccines business, although in some countries e.g. UK the Baxter Vaccine (cell culture based) was reserved for those with allergy to eggs.

In approximate terms, the additional sales revenue derived from H1N1 vaccines (~\$5-6bn) is substantial bearing in mind the value of the total industry, ~\$17bn in 2008*. For the financial community, such a large contribution calls to question whether such a windfall is sustainable, and if so, to what degree. Indeed, Novartis Vaccines in their 2009 media release already state themselves that they plan to continue delivering A (H1N1) in 2010, although “sales estimates for the year are well below 2009 levels”. This is mostly due to national governments rethinking the amount of H1N1 vaccine required and the fact the population is becoming increasingly “primed”. At the start of the pandemic declaration (June 2009), many ordered enough vaccine to cover their whole population and often assumed that 2 doses of vaccine would be required. 6 months later, in many countries, unused H1N1 vaccine has accumulated due to poor take-up in various groups and one dose being sufficient unless in special circumstances. In the US, where initial concerns were raised about supply, around 118 million doses were ordered as of 26th January 2010 with the CDC stating there is a plentiful supply. However, recent CDC estimates are that at least 60 million have been vaccinated about 20% of the total population (4) approximately 50% of typical seasonal demand.

What is the outlook for H1N1? For the epidemiological aspects, the first comment would be that influenza pandemics are unpredictable, a stance taken by the US CDC who state that while the H1N1 virus is circulating it still has the capacity to cause illness.

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Based upon the 1957 pandemic case study, some experts argue that although a “lull” in mortality may be observed, the situation may soon change with a sudden resurgence, as observed the following year in 1958. Therefore, while H1N1 vaccine supply is plentiful, the US CDC recommends vaccination should be encouraged to avoid complacency. From this it is clear that experts believe that H1N1 will be with us for some years to come.

In terms of market longevity of H1N1 vaccines, an important aspect might be that as the H1N1 virus evolves, a new vaccine might be required (as in the case of yearly seasonal influenza). It is reasonable to assume this will happen based on the known plasticity of the influenza virus hemagglutinin (HA) protein and the capability of viral “drift”. Although, manufacturers such as GSK and Novartis have stated that adjuvants included in H1N1 vaccines could exhibit some degree of cross-protection it is too early to ascertain the validity of this claim in a population-based pandemic setting. Furthermore, tetravalent vaccines that contain antigens to seasonal as well as H1N1 pandemic viruses might next be produced. Companies such as GSK have already produced data indicating that Pandemrix can be co-administered with Fluarix (5). Such vaccines may increase the average prices of seasonal influenza vaccines which have experienced downward pressure due to an increased number of suppliers. However, increased revenues from this approach will not equal those derived from a separate new H1N1 variant vaccine.

Strangely there have been reports in the lay press that manufacturers will have to “count the cost” of unfulfilled H1N1 orders. On the contrary, if one considers that H1N1 vaccines so far have almost doubled best selling vaccines such as Prevnar’s (PCV-7) peak revenues (~\$2.5bn) in 6 months, **VacZine Analytics** believes it is rather that vaccine manufacturers have experienced the biggest windfall in their history.

*Top 5 vaccine companies only

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References and Notes:

- 1) Novartis 2009 Full Year Results, 30th December 2009. Available at: http://www.novartis.com/downloads/investors/sales-results/Q4-2009-media-release_EN.pdf.4. Accessed December 2009.
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- 4) Centers For Disease Control and Prevention. Press Briefing Transcripts. January 7th 2010. Available at: <http://www.cdc.gov/media/transcripts/2010/t100107.htm>. Accessed January 2010.
- 5) GSK Corporate Press Release. Monday 09th November 2010. Available at: http://www.gsk.com/media/pressreleases/2009/2009_pressrelease_10127.htm. Accessed January 2010

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