Novartis to the vaccine industry – can we have our money back please?

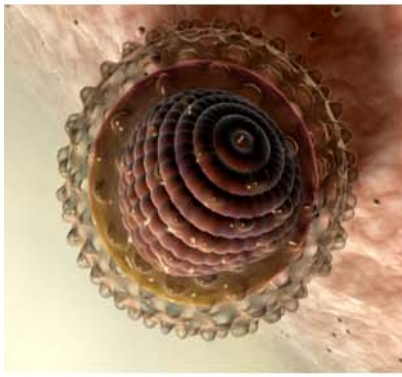
LONDON, UK----24th April 2014----ExpertREACT. After years of investment into its Chiron acquisition, Novartis has been lucky to mostly cover its initial outlay and maintain a potential stake in programs it so expensively advanced. Future rewards are dependent on a rival's performance.

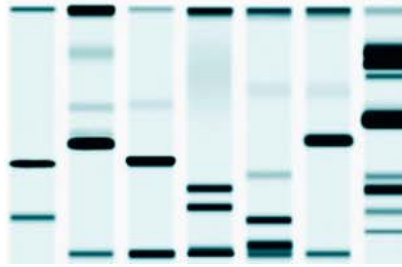
Recently, GSK Biologicals cemented its position as the most acquisitive company in the vaccine sector. On 22 April, the company announced it was acquiring the vaccines business of Novartis (excluding influenza vaccines) for $5.25 billion upfront in cash and potential milestone payments of up to $1.8 billion, with ongoing royalties (1). The last significant deal by GSK was back in 2013, when the company completed the acquisition of Okairos AG for €250 million (2). Other than GSK, the only significant recent activity in terms of M&A has been from the Japanese company, Takeda Pharmaceuticals, which acquired U.S-based Ligocyte (2012) and Inviragen (2013). Other vaccine major players in recent years have been relatively silent.

For the FY 2013 GSK sold the most in dollar terms out of the top five players recording ~$5.3bn in sales (3). According to our internal figures we estimate that Novartis vaccines sold just under $1.4 billion, having previously divested its diagnostics business in January 2014 to Griffols of Spain. Of the Novartis vaccines business, the majority of 2013 sales were derived from the seasonal influenza portfolio which is estimated around $650-$700 million per year, mostly due to US sales of the egg-based trivalent vaccine, Fluvirin. With the remaining Novartis vaccines GSK could add around $750 million per year in additional sales most of which will be derived from the Novartis meningitis portfolio which includes a quadrivalent *meningococcal* ACWY vaccine: Menveo®, the first in class *meningococcal* serogroup B vaccine: Bexsero® (4CmenB) and the serogroup C vaccine: Menjugate®. Other notable Novartis marketed brands as part of the acquisition are vaccines in the travel/endemic segment for rabies (RabAvert/Rabipur), tickborne encephalitis (Encepur) and Japanese encephalitis (Ixiaro), for which Novartis has an agreement with Valneva AG. Interestingly, GSK itself already has a presence in the *meningococcal* vaccine market with products such as Menhibrix® and Nimenrix®, to name a few. Nimenrix® is a broadly equivalent product to Menveo®.

The Novartis influenza franchise was not part of the recent GSK deal which begs the question of who would be the eventual buyer since Novartis has stated it still wishes to divest the franchise. Unlike its major influenza vaccine competitors, GSK and Sanofi Pasteur, Novartis has been slow to exploit the US switch to Quadrivalent based influenza vaccines which in some cases have enjoyed a 30 to 40% price premium on their trivalent counterparts. GSK, although not selling as much as Novartis in influenza has already launched Quadrivalent products such as Fluarix-Tetra and Flulaval (QIV) of which it supplied around 10 million doses (mainly Fluarix) to the US 2013-2014 season (3). Despite Novartis' lack of a licensed QIV product the company does have a number of QIVs based programs in phase 3 clinical testing for adult and paediatric segments and for its cell culture based vaccine Flucelvax. Any future acquirer of the Novartis influenza business would conceivably progress these programs to the marketplace and remain competitive.

As part of its media announcement GSK did state that the vaccines part of the transaction would provide 40% of the estimated total annual cost savings of £1 billion. The company stated that *"Potential cost savings would be generated from reductions in selling and administrative costs, removal of infrastructure overlaps and reduced third party contracting as well as through improvements in manufacturing costs."* (1). For the third party manufacturing, Novartis previously supplied diphtheria and tetanus (DT) bulk concentrate to GSK to become part of GSK DT containing vaccines licensed in the US. Example products are: Infanrix®, Pediarix®,Kinrix® and the adolescent adult vaccine Boostrix®, the main competitor to these GSK products being Sanofi Pasteur. Similarly, Novartis also supplied DTwP for GSK's Titranix-HB in developing world markets. DT bulk concentrates are currently produced in Novartis' Marburg plant and although the details of the shared manufacturing arrangement are not available the new acquisition will also reduce the risk level of GSK paediatric operations now that the company does not have to rely on an external partner. The ability to access DT independently has always been important to GSK, which itself attempted to produce "in-house" at a newly reconstructed €100m Hungarian plant (Godollo) back in 2006, with little success (4).





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As well as the acquisition of Novartis licensed vaccine products and potential cost savings, GSK is also accessing some Novartis pipeline programs which include a first in class pentavalent *meningococcal* vaccine MenABCWY and a Group B streptococcus (GBS) maternal vaccine, both in phase 2 clinical testing. For the GBS program, a global Phase III program is estimated to start in 2016, with estimated 3 years duration, meaning potential approval in 2020. For both these programs and the already licensed Bexsero®, Novartis has negotiated several appreciable milestone payments of $450m based on FDA approval, annual net sales thresholds and receipt of ACIP regulatory recommendations. Annual royalty payments at the rate of 10% on certain net sales of the above products have also been factored in conferring an annuity like revenue stream to Novartis.

Looking at the deal overall it seems that any surplus financial benefit of transaction to Novartis is mainly pegged to the future performance of R&D programs but under the new management of GSK. This assumes that the restructuring itself does not significantly disrupt the performance and retention of key Novartis personnel intrinsic to these programs. Some would argue that Novartis did not benefit by disrupting, relocating the Chiron organisation and initially placing Novartis people with little vaccines experience in top marketing positions. The Novartis career development culture then prompted personnel to rotate after short periods to other roles throughout the Novartis organisation so that continuity was rarely maintained. GSK having a discrete highly experienced vaccines division may not make the same mistake during its incorporation. It understands “vaccines is different”.

Considering Novartis paid around $7.5 bn for Chiron, and ploughed 8 years of investment into the loss making unit, the Swiss giant has returned $5.25 bn *plus* $1.68 bn upfront from both GSK and Grifols generally covering its initial investment (notwithstanding inflation and the remaining influenza business). It has been lucky to cover its initial outlay and also maintain a stake in the future of Chiron originated programmes that it advanced with great expense. It is ironic that the performance of a rival determines whether Novartis will ever make a profit from its troubled foray into vaccines.

References and Notes:

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4) In-Pharma. Technologist.com. September 2006. Available at: http://www.in-pharmatechnologist.com/Regulatory-Safety/GSK-opens-vaccine-plant-in-Hungary. Accessed March 2006