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Stockwatch: Oscillating fortunes

by Andy Smith

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Amgen's celebration of the *first approval* of a lipid-lowering anti-PCSK9 monoclonal antibody (Repatha, evolocumab) was short-lived. Before the end of the day Sandoz, the generic division of Novartis, received an *appeals court ruling* that will allow biosimilar competition to Amgen's Neupogen (filgrastim) in September. If that were not bad enough, before the end of the week, Amgen's PCSK9 advantage in Europe was negated by the European approval of Sanofi and Regeneron's competitor product, Praluent (alirocumab) and the *FDA approval* of Praluent as the first anti-PCSK9 antibody approved in the US. Despite denting Amgen's armour, Novartis's trials of the week were all of the operating variety as *missing analysts' consensus estimates* of sales and earnings, mainly due to its Alcon ophthalmic subsidiary, resulted in a more than 2% share price drop on the day. The analysts from JP Morgan quite rightly described the Novartis results as "disappointing," but it might well have been worse had Novartis not maintained its earnings guidance for 2015 assuming mid-July currency exchange rates.

Having been given a share price boost the previous week when the highlight of the Johnson & Johnson (J&J) results was the *sales growth* of the oncology drug Imbruvica (ibrutinib), now half owned by AbbVie, AbbVie's own earnings announcement was received with a 3.5% share price plunge. Despite beating consensus earnings estimates, it was the well-flagged effect of weak ex-US currencies on sales of its anti-inflammatory blockbuster drug Humira (adalimumab) that led

to the shortfall. Practically twisting the knife in its Imbruvica partner J&J, AbbVie suggested that it had not seen any impact from the European launch of a biosimilar Remicade (infliximab) on Humira sales that had so dented J&J's second-quarter results. With *Merck recently touting* its biosimilar Humira, these interconnected 'he said' brand, versus the 'she said' biosimilar arguments and pricing battles look likely to occupy the thoughts of payers and investors for the next few years.

Oscillating fortunes were the order of the week in companies developing drugs to treat Alzheimer's disease (AD). Expectations had been stoked, TV interviews recorded and newspaper stories written in advance of Eli Lilly's presentation of the extension data for its previously failed anti-beta amyloid monoclonal antibody *solanezumab at the Alzheimer's Association International Conference* (AAIC) in Washington, DC. In the event, the data was disappointing although while the analysts from Citigroup described it as "mixed" and those from Cowen "in-line with expectations," investors had a more critical interpretation and Lilly's shares closed down over 3% for the week. I expect this trend of underperformance to continue as the realization that the much touted separation between solanezumab and placebo that continued in the extension study was a similar numerical difference that resulted in the failure to show statistical significance in the Phase III EXPEDITION program. The effect of Lilly's lackluster clinical results at AAIC on its share price were tempered by its second-quarter *financial results*, where sales, earnings and full-year guidance all beat analysts' expectations.

But the wooden spoon of the week for share price oscillations that all fell into the negative category went to Biogen, which also presented the *much anticipated data on its anti-beta amyloid monoclonal antibody, aducanumab (BIIB037) at AAIC. While the analysts* at Citigroup described the data as "uninspiring," the negative share price reaction was greater than that for Lilly's release because expectations for the intermediate 6mg dose in its Phase Ia study were for a so-called 'goldilocks profile.' This would have been a lower rate of amyloid-related imaging events (ARIA-E) that caused *safety concerns* with the top 10mg dose, but with similar efficacy to the top dose. In the event, neither objective was achieved with the 6mg dose having an ARIA-E rate closer to the 10mg dose than the 3mg dose, efficacy that was not consistently different from placebo in one of the efficacy measures and as such, a lack of dose-response. The Biogen share price finished the week down over 25% with much of the share price fall coming in response to its second-quarter financial results and resulting slashed full-year guidance. *Slowing Tecfidera* (dimethyl fumarate) sales, first reported in April, continued in the second-quarter and as the analysts from Citigroup suggested, were partially due to growth by Novartis's competing drug Gilenya (fingolimod). Thus capped a week where many of Biogen's investors and most of its growth attributes deserted it with the analysts from Piper Jaffray describing Biogen's resulting growth prospects as "in need of fixing."

The last thing the market needs is more clinical trial failures to compound lackluster financial results. With Biogen and Lilly enrolling or having enrolled, respectively, Phase III studies on the

basis of last week's disappointing results, that would appear to be exactly what the market will be getting.

The Magna Biopharma Income fund holdings include Amgen, Regeneron, Novartis, AbbVie, Merck and Biogen.

Andy Smith is chief investment officer of Mann Bioinvest. Mann Bioinvest is the investment adviser for the Magna BioPharma Income fund which has no position in the stocks mentioned, unless stated above. Dr Smith gives an investment fund manager's view on public life science companies. He has been lead fund manager for four life science–specific funds, including International Biotechnology Trust and the AXA Framlington Biotech Fund, and was awarded the Technology Fund Manager of the year for 2007.