

LSP Life Sciences Fund Portfolio Update – Drug Pricing

On the 26th of April 2015, an article was published in the WSJ entitled *“Pharmaceutical Companies buy rival’s drugs, then jack up the prices”*. The article highlighted the business case of Valeant Pharmaceuticals. The company’s strategy of acquiring drugs it felt were “undervalued”, then raising the prices significantly post acquisition, was described as being “...one of a number of industry tactics, along with companies regularly upping the prices of their own older medicines and launching new treatments at once unheard of sums, driving up the cost of drugs.”. Furthermore, a 2014 research report, which was mentioned in the WSJ article, highlighted the fact that Valeant had “...lifted list prices by at least 20% some 122 times since the beginning of 2011...”.

This level of attention on drug pricing tactics is far from new. See for example the article in The New York Times published 5 years earlier on November 18, 2009 entitled *“Rising prices of drugs lead to call for inquiry”*. But with the highly publicised Valeant case, the issue of drug pricing has gained momentum and more media and public attention than even before. This in turn led to political reactions, including the start of an investigation initiated by two democratic members of Congress.

In September 2015, Turing Pharmaceuticals shot to fame or infamy, following a tweet from non-other than Hillary Clinton, US presidential hopeful, who strongly criticised the company for increasing the price of its drug fifty-fold overnight. The media attention for the subject of drug pricing exploded. The fact that the Turing drug was already half-a-century-old – i.e. neither new or innovative - and used to treat an infection from the toxoplasma parasite that affects more than a million people a year in the U.S. alone, increased the perception that pharma companies are using tactics that are – at the very least - unethical. As did the fact that the infection treated with the drug can be life-threatening in those who have weakened immune systems, such as pregnant women and HIV patients. Since the tweet was coming from a likely presidential candidate and she was using the words “outrageous” and “price gouging”, it increased negative sentiment. This fuelled uncertainty around future drug pricing strategies and – hence – around the future profitability of the entire pharmaceutical industry. As a result, healthcare stocks plummeted.

Since then, hardly a day has gone by when the subject of drug pricing has not made the headlines, particularly in the US but also in other countries around the world. A massive discussion has erupted around this topic and many questions are being asked and debated. For example; why are drugs more expensive in the US than in practically all other developed countries; what measures can or may be implemented to curb healthcare costs and who should implement such measure; what is the impact of drug pricing on the healthcare system; what is the impact of generics and biosimilars; what can be done to increase competition; what impact do the insurance companies have and what role do Pharmacy Benefit Managers (PBMs) play in the system? And many more. Clearly, as a result of media attention and political pressure, drug pricing and healthcare costs have become PR and IR topics of the highest priority for the healthcare industry. This change is evident from the many discussions we have had recently with several Pharma and Biotech executives, and can also be seen in their public appearances and the manner of their presentations in the media and at investor conferences.

The most recent drama unfolded around the Mylan Pharmaceuticals EpiPen – triggered by yet another tweet from Hillary Clinton. This was once again a case around a company acquiring a drug and hiking up the price. In this case the drug was for the acute treatment of severe and potentially life threatening allergy reactions. The tweet coincided nicely with the ‘back to school’ season and the

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heightened awareness of children with nut allergies. The company had increased the price of the EpiPen more than six-fold over a 5 year period. The EpiPen has a virtual monopoly on the market. Irrespective of the arguments put forward by the company in reaction to the media attention and whether those arguments are valid or not, the sentiment towards the healthcare sector turned even more negative. The revelation that Mylan's top 5 executives received USD 300 million in compensation over that same 5 year period, did not help to improve perception or sentiment for the Company. Neither did the fact that its CEO saw her salary increase by 671% over an 8 year period, earning USD 18 mln in 2015 and USD 24 mln in 2014. Mylan's CEO will have to testify before the House Committee on Oversight and Government Reform on *EpiPen* price in October.

Since the Hillary tweet on the Mylan EpiPen saying "*EpiPens can be the difference between life and death. There's no justification for these price hikes*", healthcare indices, such as the MSCI Healthcare index and the Nasdaq Biotech Index (NBI), have once again come under pressure. Compared to the general markets, healthcare as a whole has underperformed significantly for the past year. The S&P 500 has gained 6% since September 2016, while the NBI has lost 20% over that same period. Over a 5 year period, the NBI still outperformed the S&P by 120%, while the MSCI Global Healthcare index had an outperformance of almost 20% vs the S&P over the past 5 years.

The LSP Life Sciences portfolio has also been impacted due to overall negative market sentiment on healthcare. While YTD (as per September 19th, 2016), the fund outperformed the NBI, it is still down some 10% (versus net positive returns of 15% in 2015 and 48% in 2014). This is despite many positive developments this year within the Fund's portfolio of investments. Given the Fund's strategy of building a highly concentrated basket of 15 to 20 small- and mid-cap stocks that – from a fundamental point of view – offer significant growth potential, have an attractive risk/reward profile, and offer uncorrelated investment cases, we should see a further improvement in relative and absolute performance of the Fund.

Obviously, a further deterioration of overall sentiment towards the Healthcare sector will have an impact on the Fund as a whole. Also, we do expect volatility to remain high, in particular in the run-up to the US presidential elections in November. Post-election and depending on who will become President – Clinton or Trump – specific measures may well be implemented to try and curb healthcare costs. How (by executive order or via Congress) and when, remains to be seen. Clinton has issued two briefings on the matter already. One is entitled "*Hillary Clinton's Plan for Lowering Prescription Drug Costs*" and the other (published post the Mylan tweet) is entitled "*Hillary's Plan to Respond to Unjustified Price Hikes for Long-Available Drugs*". Based on her tweets, public speeches and these two briefings, the market expects a Clinton presidency to be negative for drug and biotech companies. Although one could easily argue that this indeed would be the case, there is another scenario that – in our view – is more likely.

It can be found in the second paragraph of the second Clinton briefing and reads: "*Our pharmaceutical and biotech industries are an incredible source of American innovation and revolutionary treatments for debilitating diseases. But it's wrong when drug companies put profits ahead of patients, with unjustified price increases not for new innovations, but for long-available and generic treatments – and we need rules of the road so fair competition keeps them in check. That's why, over the course of this year, Hillary Clinton has called out drug companies for outrageous and unjustified pricing practices.*".

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Based on this, we see a different – and in our view more logical - scenario evolving. One that takes “innovation” into account as a key criterium to distinguish between the good and the bad. The briefing distinguished between those companies that do develop new and innovative drugs, from those that do not. It separated the companies that do invest heavily into R&D from those that do not. Importantly, the level of innovation can and should be measured. It can be measured by the *clinical benefit* that a certain drug is offering to patients. This, in fact, is already being done. It is why clinical trials are being performed. It is to generate data to establish the safety and clinical benefit to patients. When the clinical benefit of a drug is proven – compared to other available drugs or treatments – pricing is much less of an issue. In other words, those companies that qualify as being truly innovative, e.g. developing medicines that are safe *and* provide clinical benefit, will be much less impacted in our view. The pricing of these products will be heavily influenced by payor negotiating power and competition. One telling example of how that works in practice, is the case of Sovaldi from the US biotech company Gilead Sciences.

Gilead’s Sovaldi is a prescription drug that was approved in late 2013 for the treatment of Hepatitis C (HCV). In contrast to all other HCV medications available at that time, Sovaldi actually provides a cure for the disease. Given the huge unmet medical need and Sovaldi’s amazing therapeutic benefit, the drug had the most successful drug launch in history. Practically an overnight success. In its first year of launch, it generated some USD 13 billion in sales. Its list price in the US – meaning its gross price - was USD 84,000 per patient per treatment. This triggered headlines around the world to dub it the USD 1,000 per day pill. However, Gilead has disclosed the rebate that they have offered, following negotiations with payors. That rebate amounts to 46%. So instead of the USD 84,000 gross, society actually pays only half that; for the treatment of a disease that leads to very serious complications for the patient and to very significant health costs if untreated. Since the HCV infected population is very large and the clinical benefit very significant (e.g. cure vs no cure), the health economics case is very clear and speaks heavily in favour of Sovaldi, also at a price of USD 45,000 per patient. In addition, new entrants offering similar drugs with similar therapeutic benefit, have put further downward pressure on Gilead’s initial pricing power, shifting the balance of power further towards the payors. So over and above the rebates that have already been negotiated, increasing competition from new entrants will push prices lower.

The example of Sovaldi speaks for the scenario that we believe is likely to play out over the coming months and years. It is also why we believe that the LSP Life Sciences fund is well positioned to benefit. We only invest in those companies that are truly innovative and we stay away from companies that are not. It is why we identify companies like GW Pharmaceuticals, Cempra, Spark Therapeutics, Kite Pharmaceuticals and many other as potential investment cases: they invest heavily in R&D, they work at the forefront of innovation, their products address major unmet medical needs and their products (will) provide significant clinical benefits for patients.

It would be unrealistic to expect all these companies and all our investments to become successful. Developing new medicines is a lengthy, costly and risky endeavour that requires the smartest people within the most agile companies to focus their time and energy. Sometimes certain scientific and clinical hypotheses simply do not work. Promising clinical data generated in earlier and smaller studies, often cannot be replicated in later larger studies. What works in mice all too often has been shown not to work in humans. The biological system is highly complex and far from being understood completely. Our current knowledge is particularly incomplete in highly complex diseases such as

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cancer or neurodegenerative diseases. However, we are convinced that the technological advances made over the past decades, will fuel and accelerate innovation leading to new medicines that will help to address many of the unmet medical needs society is facing today. Short term uncertainty around pricing of drugs and presidential elections, will not alter that.