HARGREAVEHALE

INVESTMENT BULLETIN

"AstraZeneca: Moment of truth approaches"

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A reassuring statement, ripe with nautical metaphors, from the Governor of the Bank of England in his latest quarterly review: "The recovery from the 2008 financial crisis has been painful for everybody but there will be a return to "normality" ..... We are navigating through turbulent waters, with the risk of a storm heading our way from the continent. We don't know when the storm clouds will move away.......but the Monetary Policy Committee will continue to chart a course through this stormy weather back to the calmer waters of steady growth". Much relief all round for us sailors.

Meanwhile, the Greeks are no longer waiting to cast their vote on June 17th, instead they are starting to vote with their wallets, withdrawing their money from the Banks. And with exquisite timing, the announcement of $2 billion of trading losses from JP Morgan with more to come are a stark reminder that the politicians should be breaking up the too big to fail/too big to manage banks, not recapitalizing them. It seems quite extraordinary that the unit at the centre of JP Morgan's trading loss of $2 billion has built up positions totalling more than $100 billion in asset backed securities and structured products, the complex risky bonds at the centre of the 2008 crisis. Specifically, the unit is said to have taken more than £13 billion (or 45%) of UK residential mortgage backed securities issued since 2009 (FT May 18th). Interest rates remain at historic lows at present but this could change radically for example if UK sovereign debt was rated anywhere near France's.

But what is really chilling is that according to the detail in the Queens speech, politicians are still proposing to protect the integrated banking system by calling for more "cushion" capital. All that does is ensure that the Banks have to continue to shrink their loan books and as a result corporates, in particular smaller corporates are starved of cash. Let investment or "casino" banks be wholly separate entities from retail banks. Let the "casino" banks take risks with their own capital and be made fully aware that they will no longer be bailed out by the tax payer. In the nautical parlance of the Governor of the Bank of England, let investment bankers walk the plank before they sink us all. Far too much of the developed world's capital is now allocated to punting extremely complex financial instruments that few understand.

It is hard to know the distortions caused by negative real interest rates in the UK and to a lesser extent in the US will play out. Both countries are operating the Indian rope trick with massive success. Since 2008, the US and the UK have printed enough money to buy over 60% of their sovereign debt issuance. They have got away with it because they have their own currency, because inflation has not been threateningly high, and because markets have believed their jargon about tackling fiscal deficits. It has also been the case that it has suited exporters such as China to prop up their client's purchasing power by supporting their currencies.

But China is now experiencing a significant slowdown in growth as its targeted export markets fade. In the UK and Europe, the consumer is clearly under pressure. In the US, evidence suggests that there is a recovery of sorts. There is a debate to be had as to the extent of the recovery but it has arrived. However, a major contributor to this recovery is export led growth led by manufacturing and highly competitive energy costs. Exports are up by 35% over the past three years. This is not at all helpful to China, which is being priced out of a number of export markets as a result of higher wage and energy costs.

Chinese policy makers are supposedly now directing a "generational change" towards internal consumption from export led growth which could have unfortunate consequences for the West. Supporting Western currencies is now not so important. The development of homogenous asset markets in Europe has in the past decade allowed the Euro to gain the status of something of a reserve currency, but not now as the fundamental folly of a common currency without a common fiscal policy reveals itself. This seems to be more important than the comparative status of real interest rates. As a result, Central Banks such as that of China are said to be steadily reducing their investment in the Euro, remaining happy to buy ten year US Treasuries on a yield of 1.7%. And Sterling, admittedly on the sidelines, is still attracting international money on roughly the same terms.

This leaves UK investors with some difficult decisions. The longer term success of the UK's Indian rope trick has got to be in doubt, but in the absence of serious inflation momentum, the illusion should be continued, over the next year helped by wage restraint and falling oil and other commodity prices. At the same time, continued Euro weakness appears to be something of a one way bet. A Greek exit triggers the perception of a possible Spanish and Portuguese exit, particularly if it is perceived to be a success. A resolution of the existing negotiations resulting in Greece and Spain remaining within the Euro, will mean repression in consumer spending and infrastructure spending and continued doubts over the viability of the Euro whenever a democratic vote takes place. Not an inspiring currency for international investors.

A strong sterling and a weak Euro is not a good combination for UK manufacturers, with over 40% of their export markets being into Europe. The latest trade figures available for the first quarter of 2012 show that UK export volumes were up less than one percent on a year earlier. That was split between a 4.4% rise in non Euro exports and a 3.3% fall in exports to the EU. That said a sharp decline in EU consumer demand would clearly be bad news. The pound is currently trading at a 42 month high of 79.8p to the Euro and it looks like continuing to strengthen. In relation to the dollar, Sterling has been trading for the last two years roughly within a range of $1.53 to $1.65. Until very recently, Sterling had steadily strengthened this year as it benefited from safe haven status, limited signs of US recovery and the threat of further quantitative easing from the US Federal Reserve. But more recently Sterling has begun to fall against the US dollar, as signs of US recovery grow stronger and as more investors start to worry that UK manufacturers could start to suffer in the event of further Euro weakness. In addition there is an increasing perception that US manufacturing is in a much stronger position than its global competition as a result of reduced energy costs, in part due to the oil and shale gas revolution. In addition, US dependence on the EU is limited, with Euro exports less than those to Canada and Mexico combined. As a result Sterling could well weaken further against the dollar with some commentators even looking for a low of 1.28, particularly in the event of further quantitative easing from the Bank of England.

This suggests that UK investors should for choice concentrate their attentions on corporates whose products are mainly priced in dollars and are addressing global markets. In this connection, we recently met with a pharma analyst who turned the investment negatives on AstraZeneca on their head and who saw the recent underperformance of the shares as an interesting longer term buying opportunity.

He spelt out the negatives which have impacted on markets as a result of which AstraZeneca shares have fallen from a high of £31 at the beginning of the year to a current price of around £26.

In macro terms, AstraZeneca in common with most other Western Pharma stocks continues to suffer from the perception that the rate of new drugs to market is slowing, whilst the ability to protect established patented drugs in emerging markets is reducing. At the same time as drugs come off patents in Western markets, prices become commoditized, particularly as Governments in the West attempt to cut back their healthcare spend. This puts a lot of Pharmas in a difficult position as they attempt to juggle their old cost base consisting of high research and development spend and high employee costs with the new realities of a globalized market.

A biomedical think tank in the US has suggested that the Big Pharma industry has cut some 300,000 jobs over the past decade as the flow of new drugs falls to a trickle. This is an expensive process not helped by the costs of EU employment protection legislation. By way of example, AstraZeneca's existing plans to reduce employee headcount of 61,000 by 7300 in 2014 will cost £2.1 billion although when finally implemented will create annual savings of £1.2 billion.

According to Forbes Magazine, the current level of failure rates for new drugs suggest that some $5 billion of research is spent for every drug that is finally approved. In the period 1997 to 2011, 139 new drugs were approved for the top twelve global Pharma companies at a total Research and Development cost of just under $800 billion. Research and Development spend per drug varied widely between Pharmas dependent on success rates. For example, the costliest drug development programme was that of AstraZeneca which spent $12 billion in research money for every new drug approved, as much as its top selling medicine ever generated in annual sales. Amgen was the most successful Pharma, having 9 new drugs approved at a cost of "only" $3.7 billion. There are lots of escalating expenses, such as clinical trials which can cost upwards of $100m whilst the combined cost for manufacturing and clinical testing for some drugs has been over $1 billion. There has been increasing criticism of the FDA in terms of delays and cost of obtaining approvals.

Despite some well known successes, the risk/reward for Big Pharma of bringing a new drug to market has deteriorated significantly which has led to some commentators to suggest that the drugs industry is now facing the wrong way. Because of the cost /success equation, Big Pharma is now concentrating, not on true breakthrough drugs, but on minor improvements to existing drugs to reduce risk and to escalate patent protection.

And patent protection of course is the major problem. The stark example given by the pharma analyst on patent expiry was as follows: Within a month of patent expiry, a product formerly selling by a patent holder at $3000 would sell at $300 and there would be 10 to 12 vendors in the market instead of one. The imminent arrival of the dreaded "patent cliff" has been haunting the pharma industry for a long time and it is now happening. With patents on many blockbuster drugs about to expire, an estimated $250 billion of sales is at risk between now and 2015. 13 out of an estimated 133 blockbuster drugs will be losing their patents in 2013.The losers will include Amgen, Pfizer, Bristol Myers, Merk, Eli Lilly, Johnson and Johnson as well as AstraZeneca. AstraZeneca will be losing Seroquel which was introduced in 1997 and has been approved for a variety of conditions from depression to bipolar disorder and schizophrenia. Seroquel has sales of over $5 billion and accounts for something of the order of 16% of the Group's total sales.

Unfortunately for AstraZeneca, this is the tip of the iceberg. Medicines that generated 62% of its annual sales three years ago will face either patent loss or competition from lower priced copies by 2014. And it gets worse because BRIC governments are becoming much more aggressive in their dealings with Western Pharmas.

In common with other Big Pharmas in the West, BRIC governments and regulatory authorities are increasingly challenging existing patents recognized in developed markets. In particular they are challenging upgrades to existing drugs on patent which result in further prolonging patents. Two months ago, the Indian Patent Office announced that it has issued its first compulsory license to an Indian drug manufacturer to manufacture for the domestic market a drug which has so far been imported under the name Nexavar. This is an anti cancer drug for which Bayer had been granted the patent in 2008. Novartis is also fighting the rejection of a patent on another anti cancer drug. Increasingly generic drug manufacturers are challenging drug patents on the grounds that the patent rights holders seem unable to supply the market in sufficient quantities and at affordable prices. The fact is that Emerging Market Authorities now seem to be in the negotiating position to challenge the West in many areas which were in the past dominated by the developed world. And at the same time, because of the slowdown in new drug creation, prices are gradually being commoditised as drugs gradually come off patents which remain still protected by Western courts.

As a result of the changing environment, Big Pharma management are being tested as never before and the same can be said for investors' nerves. The attraction for investors is that management might be capable of turning such negatives into opportunities. Perhaps AstraZeneca is an extreme example of the possible opportunity for investors because it looks as though it is both the highest cost developer of new drugs whilst facing one of the highest rates of patent attrition in the immediate future.

AstraZeneca management still has some useful aces up its sleeve. The first is not all doom and gloom in the existing drugs portfolio. There remains substantial embedded value. A typical analyst's valuation consisting of a net present valuation estimate based on future cash flows from existing and new drugs is of the order of £35 per share. Like any NPV assessment, it is subject to many variables but AstraZeneca has a wide range of drugs addressing cholesterol, schizophrenia, asthma, hypertension, prostate, cancers, heart failure, etc. In addition it has some very interesting new drugs which have recently been patented. A key new drug is Brilinta for thrombosis, which is achieving good acceptance rates amongst US doctors who appear to prefer the product to market leader Plavix because of lesser side affects. Plavix recently notched up sales of $10 billion. Another key drug, Fostamatinib is currently trialling phase three. These two drugs could ratchet up sales of over $1 billion within three years.

Equally important is the rate of attrition in Western markets of major established products such as Crestor for Hyperlipdemia, Seroquel for psychotic disorders, and Nexium for ulcers. These three drugs should still achieve sales of $8 billion in 2016, compared with $11billion today, despite Seroquel coming off patent. This rate of attrition although substantial, still gives management time to reconsider the options available going forward. Management need time, and fortunately a strong balance sheet does give them some breathing space.

In terms of the existing balance sheet, at the end of 2011, the Group had net cash of just under $3 billion. Cash generated from operating activities amounted to $8 billion. During 2011, the Group spent $5.3 billion on research and development. Capitalized at $57 billion, the existing management has committed to a continuing share buy back programme which cost it $5 billion in 2011 and a 50% dividend payout which cost a further $3.7 billion. At current prices, the forecast dividend yield is 7.2% for 2012 rising to 8.2% next year. The earnings multiples are 6.7 and 6.5 respectively.

The stockmarket, therefore is valuing Astra on a yield and earnings basis which suggests that it does not believe in the sustainability of cash flows going forward. Certainly, the extent of the share buy backs and dividend payments suggests that the existing management has little idea of how to deal with the dilemmas presented by the changing macro environment.

In fact, there is a message from existing management as a result of the sheer size of these payouts. The management is effectively suggesting that the best strategy for shareholders rather than employees would be to decide that AstraZeneca, as structured, is no longer a going concern in the longer term. Run the company for cash, slash research, development and all capital spend. At the same time reduce headcount, bearing in mind that recent figures on headcount reduction suggest a two year payback. You only have to look at the figures to see that it would be possible to generate cash flows of $20 billion a year fairly quickly.

A competing global Pharma could have the same idea. The last few years have certainly seen an increase in acquisition activity as a result of global pressures. For example, Sanfi, Novartis, AstraZeneca itself, Roche, and Bayer have over the past two years spent $140 billion on acquisitions and a further $14 billion on licensing deals and bolt ons. Sanofi bought Genzyme for $20 billion, Roche bought Genetech for $47 billion, Novartis paid $14 billion for Alcon. Interestingly at the same time Big Pharma has been a big dividend payer ($114 billion) and buy back merchant ($52 billion).

Buy backs and dividend payouts often happen when an industry is in a state of flux and Big Pharma is no different. Such uncertainty can spell opportunity for investors but there are also clear pitfalls. A panicked management, for example could use up cash and leverage to make an expensive and foolhardy acquisition. Clearly during such periods of uncertainty, management is key. This is especially true of AstraZeneca where the CEO has recently resigned with a replacement for him likely to be announced during June.

The previous CEO was a Pharma man born and bred from the ranks of Merk. At such times of change, corporates need a fresh approach, which is why the recently appointed Chairman, Lief Johansson looks an interesting choice. Lief was an executive at white goods manufacturer, Electrolux and more recently the CEO of Volvo, whose automotive business he sold to Ford, developing the highly successful Volvo truck operation. He has a reputation for thinking and acting in an original manner.

Equally important is the strategy review which will clearly be an important part of the Chairman and CEO's remit. Part of that strategy could well be to embrace the change which is being forced on the industry. This would involve accepting that the opportunity lies with the emerging middle classes in emerging markets. These customers, like customers for Volvo's, are attracted to global brands like AstraZeneca and would be prepared to pay a premium price for both patented but more importantly for generic drugs. This would mean spending money on distribution, controlling supply chains globally in preference to large research and development spend. It would mean only spending on late stage drugs moving through the stage three FDA approval process. It would mean outsourcing research and significantly reducing direct employee spend.

The stockmarket is clearly looking carefully towards the new management appointments and the likely changes in strategy which will result. The overall key for earnings sustainability going forward is generating significant volumes of low cost generic products to compensate for lower prices as a result of products coming off patent. Investors should do the same, because if sustainability of earnings going forward can be seen as realistic, then a rating change could produce a real opportunity. The key is management.

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