

Pre-election pricing fears are overdone - International Biotechnology upgrade to Positive

The US political headlines are holding back the biotech funds but the details suggest the impact could be more benign for innovative drugs. Post the presidential elections the headwinds should wane and we believe this is an attractive entry point. The current PE for the sector is 20% below its 5 year average and discounts are attractive, in our view. Whilst we do not know when discounts will narrow, we believe the sector will continue to benefit from structural tailwinds and the low valuations should encourage M&A. We are upgrading our recommendation on IBT to Positive as it trades on a 15% discount. We remain Positive on BIOGs and Neutral on BB Biotech.

One of the few areas of the market where there is value. Post Hillary Clinton's latest EpiPen comments a couple of weeks ago, the market has fallen back and Biotech is one of the few sectors of the market offering reasonable value coupled with growth. The Nasdaq Biotech Index (NBI) remains 29% below its 2015 peak (to 05/09/15). Based on our "Under the Bonnet" analysis (Fig 2) the Biotechs trade on a 2016E PE of 17x and 2016E EV/EBITDA ratio of 14.5x, a small discount to their large cap Pharma peers. This discount increases in later years due to the greater growth rates of the biotechs. Furthermore, despite their strong forecast growth rates, the large cap biotechs trade at a 15% discount to the S&P 500 PE multiple.

What can the politicians do? Both presidential candidates say they are determined to reduce drug pricing. However, the managers believe that these risks are priced in. They say that if Hillary Clinton gets elected, it will be difficult for her to get significant reforms through a Republican house. Furthermore, whilst politicians want to prevent exploitative price rises, they do not wish to stymie innovation. As a result, innovative biotech companies' funds should be less exposed to price controls with the specialty and generic pharma companies more at risk. In this report we have included the managers' thoughts regarding this issue.

M&A suggests industry is less worried about the politics. Since the beginning of the year the NBI has declined by -17% (to 05/09/16). These declines have led to a fall in IPOs; but M&A is continuing. In August, Medivation announced it was to be acquired by Pfizer for \$14bn, a 21% premium, and earlier in the year Shire acquired Baxalta for \$32bn. This suggests that although politics are an issue, it is not a sufficient concern to freeze investment activity by industry participants.

IBT upgraded to Positive. The fund is trading at what we view as an attractive discount of 15%, the widest discount in the sector and is currently buying back stock. Furthermore, the trust has been the best relative performer over the last year falling -4% (NBI (£): -5%). It has been successfully exploiting the M&A wave e.g. Medivation was the 7th largest holding at 31/07/16. The manager believes the M&A activity will continue.

Stocks reviewed

INTERNATIONAL BIOTECHNOLOGY TRUST PLC	
Recommendation	Positive from Neutral
Price	489p
BB BIOTECH AG	
Recommendation	Neutral
Price	CHF49.10
BIOTECH GROWTH TRUST PLC	
Recommendation	Positive
Price	680p

Prices are as of close 06 September 2016

All sources unless otherwise stated: Company data, FactSet, Stifel estimates

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Drug Pricing – How serious is the political threat?

The Nasdaq Biotechnology Index (NBI) peaked in July last year but declined sharply after U.S. presidential candidate Hillary Clinton attacked the drugs industry for “price gouging” saying that if elected she would be proposing new regulation that would lower drug prices. Donald Trump has followed suit with a similar commitment and the US Congress has held hearings to discuss drug pricing.

As a result of the pricing concerns, the Nasdaq Biotechnology Index declined 40% from its peak in July 2015 until late June 2016 and still trades at 29% below its peak. In late August, these drug pricing concerns re-emerged as Hillary Clinton attacked Mylan for raising the prices of its EpiPens. Mylan has raised the prices for EpiPen by over 400% since 2007, when it acquired the rights to the product.

The managers of the biotech funds believe these pricing issues are principally a cause for concern for specialty and generic pharma companies, which invest little in R&D, but acquire the rights to drugs and then attempt to generate a return on their investment through price increases.

Whilst we accept that the managers are obviously biased towards their sector, we are inclined to agree with their views. Innovation and drug discovery is an extremely expensive, time consuming and high risk business. To continue to encourage drug discovery there needs to be generous rewards to those who succeed in developing new solutions given the significant financial risks that are faced as part of the discovery and approval process. Furthermore on Friday (September 2nd), Hillary Clinton published “*Hillary’s Plan to Respond to Unjustified Price Hikes for Long Available Drugs*”. This plan concurs with our view, as she highlights that her issue is not with new, innovative drugs but with exploitative price hikes for long available and generic treatments.

Below we present the thoughts of each of the managers on this pricing issue.

International Biotechnology Trust

“The pharma/biotech business model is simple. New innovative products (drugs) are “protected” by a combination of intellectual property (patents) and government regulations. This limits competition and companies can charge high prices until this protection ends, usually 7-15 years later. After this period, government agencies regulating drug approvals will make original results available for generic/specialty pharma drug producers to market inexpensive copies of the original drug. The price gouging that politicians in the US are irritated about is related to the non-innovative end of the market, where some manufacturers have increased the price of old cheap drugs to the level of innovative drugs (e.g. Daraprim), and where there has been excessive price hikes of drugs that does not reflect new innovation (e.g. EpiPen). This is abuse of the business model and we agree that this ought to be tackled.”

“International Biotechnology Trust currently invests predominantly in “biotech”, highly profitable innovative drug companies, and not in the low margin generic/specialty pharma that is not “biotech”. Unfortunately the well-known NASDAQ Biotech Index, for reasons that we do not understand, also include generic/specialty pharma companies, thus confusing an investor. It is our firm belief that the fundamental pharma/biotech business model will remain intact, and that potential future changes from the law maker will improve the model, both at the innovative end, but more importantly at the generic end of the market. Yes, Hillary Clinton was outraged by price gouging by generic/specialty pharma companies, but she also presented an initiative on Technology and Innovation, defending intellectual property rights, and proclaimed the importance of innovative industries for the US economy” (Manager comment, Aug 2016).

The Biotech Growth Trust

“While we acknowledge that strong pricing power is an important factor for biotechnology business performance, we believe the sector’s growth is fundamentally driven by innovation and the approval of novel drugs. Most of the biotechnology drugs on the market or in development target severe diseases with high unmet medical need, and are differentiated from existing treatments by higher efficacy or

better safety. Although biological drugs are expensive, the cost is typically justified by significant downstream savings to the healthcare system or by significant improvement of patient lives. In contrast, many specialty pharmaceutical companies tend to forgo significant research and development and instead purchase existing drugs that they market aggressively to patients and physicians. We believe that this specialty pharmaceutical business model is less sustainable in the current political environment compared to the traditional biotechnology model focused on innovation. Over the long term, we expect innovative drugs that provide a meaningful clinical benefit over standard of care will continue to command premium prices.”

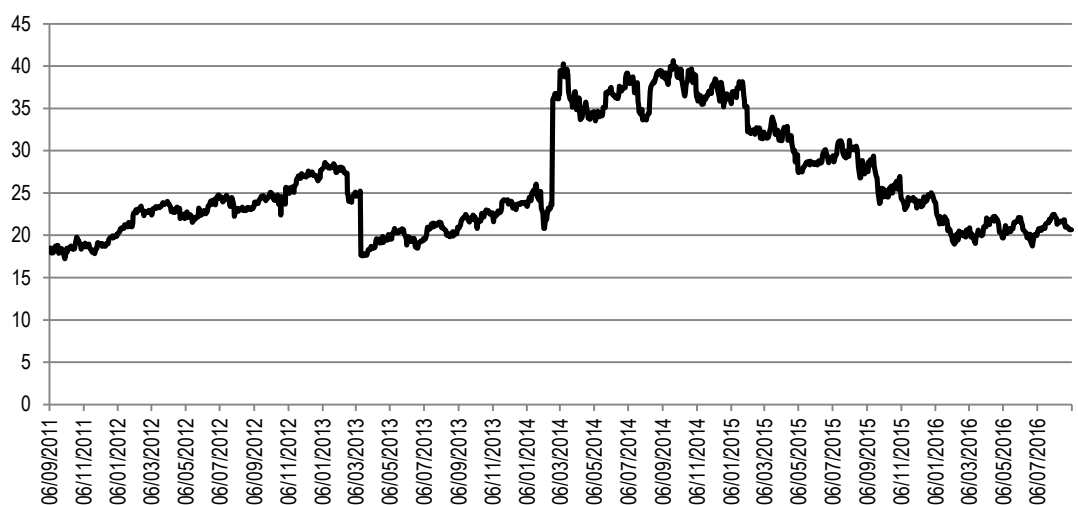
“Moreover, we continue to believe efforts to control drug pricing and reimbursement by government will not pass into law in the near or medium term, regardless of who is elected President. Nevertheless, in a U.S. election year, we expect drug prices to remain a topic during the presidential campaign, and this issue may be an overhang on the sector through November. As long-term investors, we remain focused on the sector’s strong fundamentals.” **(Annual Report to 31/03/16, published late May 2016)**

BB Biotech

“Although being well-understood and accepted that investing in innovation does require attractive capital returns, recent examples within the specialty pharmaceutical industry have reinforced public pressure. Such companies have acquired older marketed products and implemented massive price increases for these drugs, thus turning the classical “investment and return cycle” upside down. Of even bigger importance than the pricing power is a predictive and well-functioning regulatory environment. The US FDA is currently interacting with the industry to improve the review process. The new PDUFA guidelines, the PDUFA VI, are expected to be approved and implemented in 2017. We are actively monitoring the progress and potential implications of the new guidelines, with expectations that they will either maintain or improve on the PDUFA V. With the US biotechnology industry an important contributor to the US high-tech industry, we expect that innovation will continue to be attractively priced and reimbursed in the US.” **(Annual report to 31/12/15, published 19/02/16)**

“**BB Biotech’s** strategy meeting in June included an expert panel on global drug pricing and reimbursement trends. Encouragingly, genuine innovation is anticipated to command premium pricing as long as innovators address market price realities. Experts believe that innovation continues as the strongest foundation for attractive prices. Health economic arguments are also gaining in importance and can help solve the equation of payer profitability – which remains their first priority. **BB Biotech** continues to monitor the political and legal landscape for healthcare reforms and changes but expects incremental rather than dramatic change particularly in the US.” **(June Interims, published 22/07/16)**

Figure 1: Nasdaq Biotechnology Index - Current PE Multiple 5 years to 05/09/2016



Source: Thomson Reuters

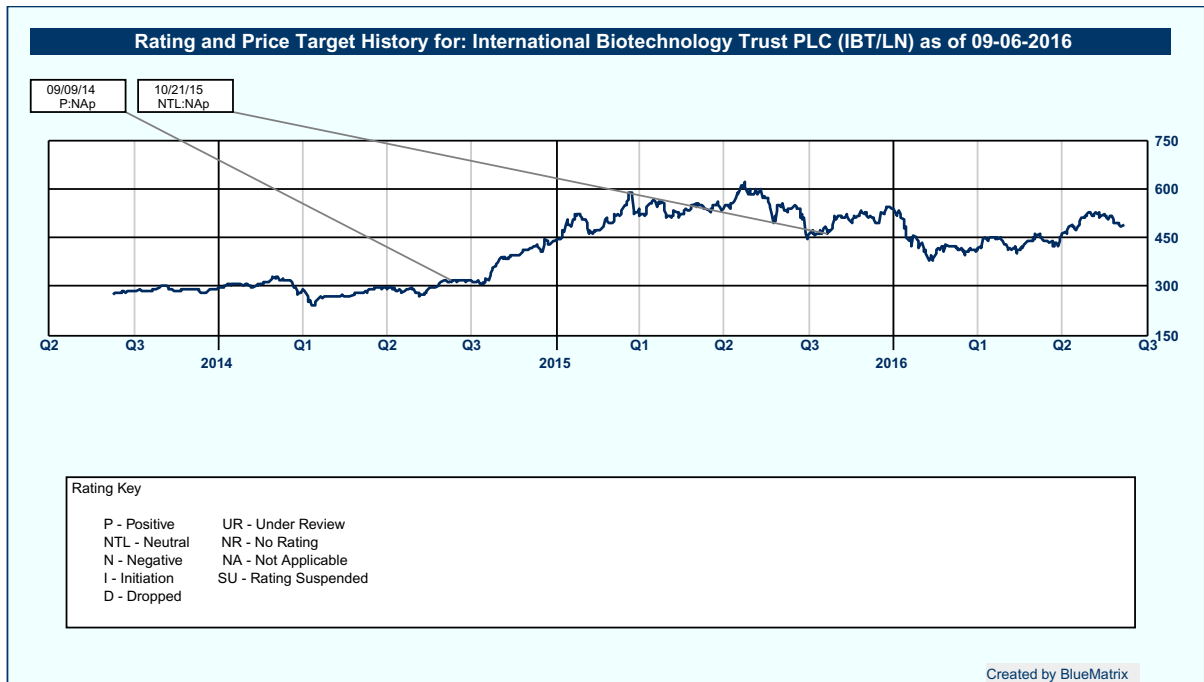
Figure 2: Global large cap Biotech vs US Pharma valuations metrics

	Share price (local currency)	Market cap (\$bn)	Year end	PE 2016 (x)	PE 2017 (x)	PE 2018 (x)	EV/EBITDA 2016 (x)	EV/EBITDA 2017 (x)	EV/EBITDA 2018 (x)	5 Year EPS CAGR (%)	PEG
US Pharma											
AbbVie	64	102	Dec	13.3	11.2	9.7	12.2	10.4	9.0	11.2	1.0
BMS	53	88	Dec	20.1	17.4	15.4	21.1	18.0	15.8	20.6	0.8
Eli Lilly	77	85	Dec	21.4	18.8	17.0	18.4	16.1	14.6	12.9	1.5
J&J	119	334	Dec	17.8	16.8	15.8	14.4	13.7	12.9	6.5	2.6
Merck	63	179	Dec	16.8	16.4	15.0	13.4	13.5	12.5	6.4	2.6
Pfizer	35	219	Dec	14.1	13.1	12.1	12.1	11.2	10.5	6.3	2.1
				17.3	16.6	15.2	13.9	13.6	12.7	8.9	1.9
Biotech											
Actelion	167	19	Dec	22.0	21.8	17.9	19.4	19.6	15.9	13.0	1.7
Alexion	124	24	Dec	26.6	20.7	16.0	22.7	17.8	13.9	28.1	0.7
Amgen	170	129	Dec	14.9	13.6	12.7	13.0	12.1	11.4	7.9	1.7
Biogen	314	74	Dec	15.6	15.1	13.8	11.6	11.6	10.8	8.9	1.7
Celgene	105	84	Dec	18.5	15.1	12.5	16.0	13.1	11.1	22.5	0.7
Gilead	77	116	Dec	6.5	6.6	6.7	6.5	6.8	7.1	2.2	3.0
Regeneron	389	40	Dec	35.6	26.9	21.5	24.3	19.8	15.3	24.3	1.1
United Therapeutics	123	6	Dec	7.8	9.0	9.7	5.4	5.9	6.7	5.6	1.6
Global Biotech				17.0	15.1	13.3	14.5	12.6	11.2	11.0	1.6
Biotech Premium to US Pharma				-2%	-9%	-13%	4%	-7%	-12%	+24%	-13%

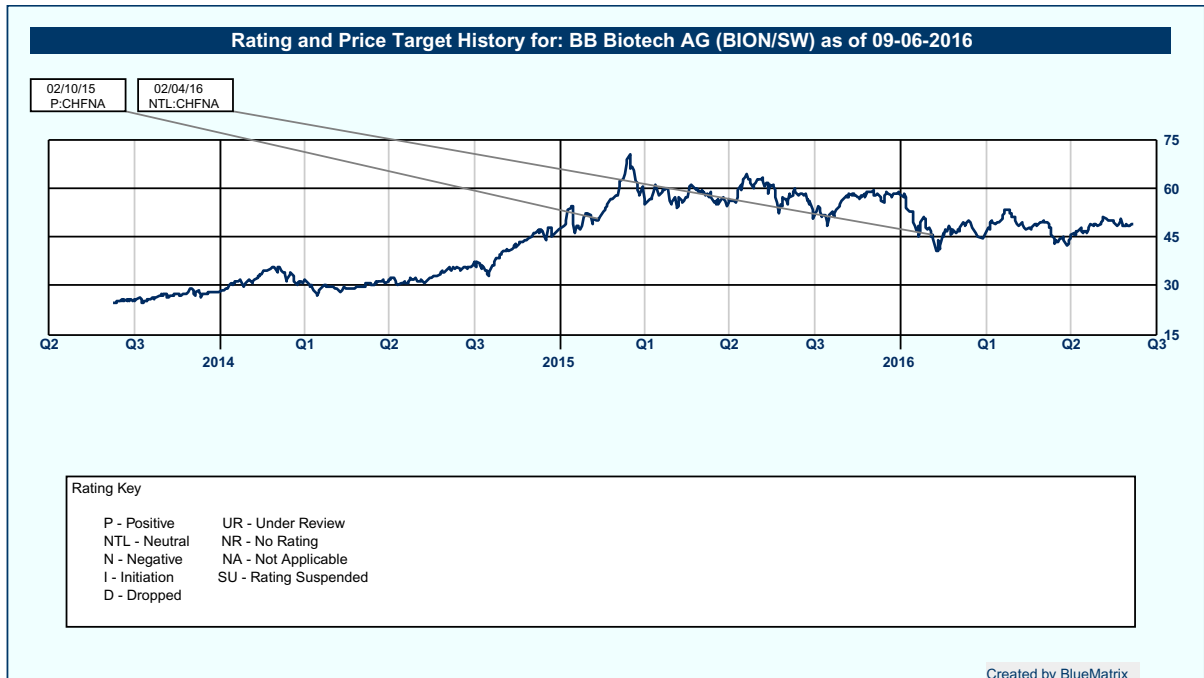
Source: Thomson Reuters 02/09/16, EPS CAGR 31/08/16

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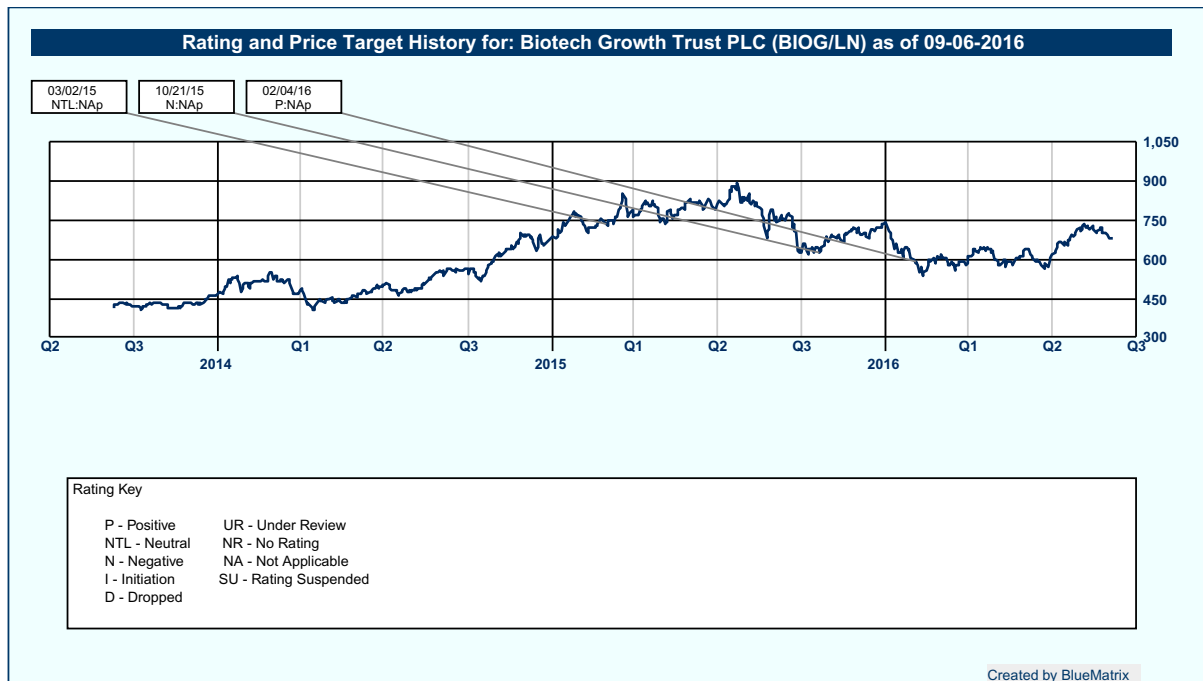
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