BIOPHARMA
SET TO BOUNCE BACK AS POLITICAL UNCERTAINTY FADES

SUMMARY

WEAK 2016 RESETS EXPECTATIONS
Biopharma suffered a poor 2016, after years of strong performance. Political rhetoric was the main source of volatility, but the sector also suffered from weak execution. We think 2016 helped reset expectations and created an attractive opportunity to build long-term positions. Uncertainty will linger in the first half of 2017, but overall we expect a better relative and absolute performance this year.

THE OUTLOOK IS BETTER FOR 2017
Key drivers of the improved outlook include the following: we are only midway through a major scientific innovation wave and late-stage clinical trials are set to mature, particularly in the second half of 2017 and even more so in 2018; EPS and revenue growth expectations are beatable; valuations are attractive and will be boosted by buybacks and M&A.

PRICING CONTROVERSY SHOULD TONE DOWN
Importantly, we also expect the political controversy on drugs pricing in the US to tone down, probably in the second half of the year. We think the Republican administration will ultimately adopt a more pro-business agenda. The sector will remain volatile until investors have better clarity over which views will prevail—probably within the first 100 days of the Trump administration.

INVESTMENT CONCLUSIONS
Biopharmas are attractive based on current multi-year low relative valuation, global trends and sector specific catalysts. However, clarity will likely be needed over what changes will be implemented by the new US administration before the sector can durably outperform again. The second half of 2017 looks to us more likely to bring performance, but we do not think that current positions should be reduced.
A DISMAL 2016

After having been one of the market-leading sectors for a number of years, biopharma recorded a dismal 2016. Its underperformance compared to the S&P 500 was its worst since 2002.

In hindsight, 2016 looks compromised from the start, given multiple years of outperformance, excessive positive sentiment and a high bar from 2015 in terms of drug approvals, revenue growth, product demand and clinical successes. The Nasdaq Biotech index was on a seven-year double-digit growth streak.

Political rhetoric in the US was the main source of volatility last year: drug pricing was central to Hillary Clinton’s White House bid. Politicians were very successful at oversimplifying the issue and finding extreme cases of fraudulent-like behaviour in order to reinforce their message. This resonated with voters, who are particularly angry about direct drug costs such as deductibles and co-pays.

Political rhetoric was the main source of volatility last year

However, execution was also weak in 2016, in contrast with three stellar preceding years: disappointing guidance to start the year, spectacular late-stage failures, few new drugs approved, and a general lack of positive surprises.

These issues explain the large outflows from passive and active biopharma funds and the compression in single-stock valuation multiples last year. We estimate that 2016 outflows wiped out all the inflows from 2014 and 2015.

A BETTER OUTLOOK FOR 2017

What does that mean for 2017? First and foremost, we think that 2016 helped reset expectations, and created an environment where patient investors have an attractive opportunity to build long-term positions. There are good entry points in both large capitalisations and in riskier innovative companies. We acknowledge that uncertainty will linger in the first half of the year, especially until the policies of the Trump administration become clearer, but overall we expect a better relative and absolute performance for 2017.

There are four important reasons for this:

1. Innovation wave. We are only midway through a major scientific innovation wave, considerable unmet needs remain, and the use of “breakthrough designation” for pipeline drugs by the Food and Drug Administration (FDA) is at an all-time high.

2. Beatable expectations. EPS and revenue growth expectations are beatable, and valuations are very attractive.

3. Buybacks and M&A. Capital allocation for buybacks and M&A will help increase valuations.

4. Politics to fade. We expect the political controversy on drugs pricing to tone down at some stage in 2017, probably in the second half of the year.

LATE-STAGE TRIALS ARE SET TO MATURE

On innovation, biopharma companies need clinical successes to support their share prices. Late-stage clinical trials are set to mature in various therapies, particularly in the second half of 2017 and even more so in 2018. As markets begin to anticipate this, there is the potential for a strong second half of the year, especially if it coincides with less populist rhetoric on drug pricing. This will be an important year for oncology, with multiple trial results in solid and liquid cancer. Elsewhere, gene therapy technology is maturing and orphan diseases continue to attract large investments to tackle rare life-threatening diseases.

There is the potential for a strong second half of the year

As investors have mostly fled these stocks and expectations have tempered, any positive developments stand to create a more constructive view of the sector and increase valuations in aggregate. Indeed, this trend is already occurring, as funds have started to flow back into the more promising smaller mid-cap (SMID cap) names—these have outperformed the S&P 500 since the Brexit vote in June 2016.

VALUATIONS ARE AT MULTI-YEAR LOWS

On growth, expectations of 5.4% for revenue and 8.7% for EPS are beatable (see chart 1). In contrast to the elevated expectations going into 2016, growth expectations for 2017 have continuously come down during the past year for profitable biotechs, and have been
stable the last four months for pharmas. In addition, valuations are at multi-year lows (see chart 2), in marked contrast to the start of 2016, when valuations were high.

**M&A IS ON THE CARDS**

On capital allocation, deployment will be a focus in 2017 even without a tax law change, but a cash repatriation bill would further accelerate M&A and buyback trends. Mega-cap biopharmas have, in general, extremely strong balance sheets with net cash positions and generate very high free cash flows, but have difficulties in meaningfully growing the top-line. Meanwhile, innovative SMID biopharmas with late-stage clinical assets face hurdles in efficiently commercialising new drugs. This creates incentives for both to work together, or for the largest companies to buy innovation outright.

Recent buyouts have been made at significant premiums

Managements of five large-cap companies have publicly disclosed interest in M&A, and we estimate their aggregate firepower at more than USD250bn; a mega-deal is not excluded either. We consider that at least 15 companies are potential targets, and recent buyouts have been made at significant premiums, highlighting that current share prices are attractive. For example, Johnson & Johnson is interested in acquiring Actelion at a price 90% higher than the November market value. Last autumn, Pfizer acquired Medivation for a price 2.7x higher than the trough market value of March 2016. A wave of M&A will increase interest in the sector, resulting in expansion of valuation multiples.

**UNCERTAINTY OVER POLICY IS A CONCERN**

On drug pricing, although we do not expect the drug pricing rhetoric to disappear completely, we think that the Republican administration will ultimately adopt a more pro-business agenda and will focus on replacing Obamacare, not on implementing drug price oversight. That said, recent declarations by Donald Trump have added to uncertainty over his real intentions—his public messages are at odds with the positions of his nominees. Tom Price, Trump’s pick to lead the Department of Health and Human Services, which oversees the FDA, is an outspoken critic of Obamacare and advocate of less government control of healthcare in favour of free-market solutions. He has declared that his priority is to reform the FDA in order to put greater focus on the need for new and innovative products—a far cry from imposing price controls. Moreover, vice-president Mike Pence served until 2017 as the governor of Indiana, whose largest employer is Eli Lilly.

The sector will therefore remain volatile until investors have better clarity over which views will prevail, Trump’s tough declarations on drug pricing or the more constructive views of his team. The first 100 days should provide enough insight for investors to better assess the political risk. The fact that mutual funds and biotech ETFs saw inflows during a week when Trump stated that pharma is “getting away with murder” is encouraging, and suggests that a significant “political” risk premium is already priced in. On aggregate, some 25% of biopharmas’ revenues are exposed to US public healthcare plans, so the current 15-20% discount over average relative valuation already reflects a significant threat to pricing.

The first 100 days of Trump’s term should allow for a better assessment of political risk

**UNDERSTANDING THE PRICING ISSUE**

Understanding the debate around pricing is crucial to assessing prospects for pharma companies. Spending on drugs in the US is around USD350bn annually, or around 14% of the country’s total healthcare expenditure. A particularity of the US system is that total costs are evenly split between the government and the private sector, usually employers. The government covers various programmes, such as Medicare (34% of total healthcare spending) for the elderly, Medicaid (10%) for the poor, and Veterans Affairs (4%) for the armed forces. The rest of the population is mainly covered by commercial plans chosen by employers, or privately subscribed to by individuals.
PUBLIC DISSATISFACTION IS HIGH

The high level of dissatisfaction among the general public, both employers and employees, is directed towards private plans. Insurance premiums have tripled since 1999, resulting in ballooning costs for employers and employees. For instance, the annual insurance premium paid by an average American household employed by a small or medium-sized company jumped from USD1,831 in 1999 to USD6,597 in 2015, while employers’ participation rose from USD2,683 to USD5,466 over the same period, both widely outpacing core inflation (see chart 3). Making things worse, in order to decrease premiums paid, half of all employees have enrolled in plans with deductibles higher than USD1,000 (see chart 4). This fuels a general perception of paying more for less coverage.

Unfortunately for biopharmas, co-pays and deductibles are much higher than for services such as hospitals and doctors, for which patients face very low, if any, payments. This further reinforces the popular theme that biopharmas are responsible for rising costs, even though in fact their contribution to total health costs has remained constant since the 1960s, at around 14%.

The populist appeal of campaigning against drug costs is therefore very powerful, and the theme was used extensively by Hillary Clinton and Bernie Sanders, as well as by Trump, in the US primaries and presidential election campaign. The problem for politicians is that the issue is asymmetrical. Politicians have an influence on public plans, which are well liked by the public, but lack influence over commercial plans, which are the real source of popular anger. Public plans are appreciated because: first, they are within budget; second, Medicare patients, a powerful voter group, are satisfied with coverage for both services and drugs; and third, contrary to Trump’s declarations, drug prices are already extensively negotiated. Indeed, drug prices are structured as additional discounts to commercial plans, which gives the government a path forward if the commercial plans effectively address costs for their clients.

Politicians lack influence over commercial plans, which are the real source of popular anger

The Congressional Budget Office has stated on multiple occasions that directly negotiating drug prices would not significantly change costs for the government. Government price-negotiating authority does not feature in House Speaker Paul Ryan’s 37 page healthcare blueprint, nor does it have the support of Price, Trump’s nominee for health secretary.

On the commercial front the dynamic is different: while drugs represent only 14% of total healthcare costs, they are 30% of costs for private employers, and rising more rapidly. Commercial plans are thus more motivated to control their drug costs, and have made considerable progress in doing so, particularly over the last couple of years. They have addressed higher costs primarily in two ways: shifting more costs to employees and tightening control over formularies (lists of prescribable medicines) using non-financial tools—either restrictions or outright exclusions.

A MIDDLE GROUND MAY BE FOUND

We have three main projections for the pricing issue:
1. Commercial plans will continue to put pressure on drug formularies, including to control areas where there are alternatives to existing drug-based treatments, such as diabetes, anti-inflammatory, cardiovascular diseases.
2. The pressure will also affect supply chain participants such as distributors, drug retailers (pharmacies) and generic drug companies.
3. On the government side, we do not expect the Republican administration to engage in direct control of drug prices—although this cannot be ruled out. However, we think that politicians will need to achieve some change in order to save face. A reversal of the “du- al-eligible” decision seems the most likely middle-ground with Democrats: these are people eligible for both Medicaid and Medicare plans, currently covered under more expensive Medicare plans, who would be switched to cheaper Medicaid plans. Such a scenario would cut biopharmas’ revenue by 1.5-3%.

CHART 3: EMPLOYERS ARE RAISING EMPLOYEE PARTICIPATION IN LINE WITH THEIR OWN COSTS

Source: Pictet Wealth Management, Kaiser Family Foundation, Health Research & Educational Trust
FOCUS NOTE

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Finally, we cannot rule out that the drug industry will find a smart way to respond to the current environment and reduce public anger. This is focused on direct drug costs such as deductibles and co-insurance. If biopharmas find some way to help insulate the public from these costs—as they have done in the past, for example through endowments and foundations to cover some premiums—it could de-fuse the political controversy surrounding drug costs.

SECTOR STRATEGY

At the company level, US biopharmas are better positioned than their European peers to navigate pressure from commercial payers, as their drug portfolios’ relative exposure to competitive therapeutic categories is less significant. Therapeutic areas like oncology, orphan disease, HIV, vaccines and multiple sclerosis are more insulated from commercial-payer pressure, while diabetes and inflammatory conditions will face increasing scrutiny. Profitable and innovative US companies with market values between USD20bn and USD100bn look to us to offer the best balance of growth and profitability. The very large caps will all face headwinds to grow revenue and will likely be forced towards M&A in the medium term, an issue that generally applies to European biopharmas as well.

CHART 4: WORKERS ENROLLED IN A PLAN WITH DEDUCTIBLE >USD1,000

Source: Pictet Wealth Management, Kaiser Family Foundation, Health Research & Educational Trust

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