

Pharma and Biotech Markets: Mostly Sunny, But An Uncertain Forecast

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For most of the last ten years there has been a lot to be happy about in the pharma and biotech industry. The number of new drugs approved and under development escalated for both pharma and biotech companies. A host of new methods, such as immuno-oncology, CRISPR, personalized medicine, stem cells, and biologics have opened up a surge in productive innovation. We are beginning to see drugs that cure difficult diseases rather than just extend life—an extraordinary development. There have even been recent U.S. regulatory and funding changes that are intended to increase government funding and ease the drug approval process, although time will tell if the actual results match the intent.

The access to equity capital and the valuations of pharma and biotech organizations in the public and M&A markets soared until the end of 2014, in part because of these positive developments.

Since then, the innovation successes have continued, but there have been times when heavy clouds have appeared in terms of the stock market, access to capital, pricing controversies, and uncertainties around the ongoing structural changes in a number of the major markets such as the U.S. and China. There also was a slowdown in FDA drug approvals in 2016 in the U.S. with only 22 approved, but we all hope that the slowdown was only temporary.

Share prices and public valuations have been volatile since late 2014, with industry uncertainties and the drug-pricing controversies to blame. Public biotech shares were hit particularly severely and, as a result, the IPO market started to cool off in the second half of 2015 and plunged in 2016. Secondary offerings were strong in 2015, but then fell precipitously in 2016. This is creating a difficult equity financing environment for biotech companies, which, in turn, has limited the choices available to biotech firms to continue to fund their companies. This has contributed to a surge in M&A activity in 2015 and 2016 as many biotech companies have had to sell their companies earlier than they would have liked, often just after they achieved certain clinical trial milestones.

The rest of this article will provide the data behind these historical observations through the end of last year, but will go on to explain what happened in the first quarter of 2017 and beyond. We will also explore the implications of these trends for decisions being made by senior executives and investors in the pharma and biotech industries.

Pharma Equity Market Performance

During 2016, the equity markets plunged in January and February and then recovered in March. Global markets saw a drastic dip again in late June in the wake of the Brexit decision, but quickly recovered. After the U.S. Presidential elections, the markets rallied strongly.

As a result, 2016 saw the S&P 500 increase 11.2% from the beginning of the year and the FTSE 100 increased by 17.2%.

In contrast, the Young & Partners (Y&P) pharmaceutical indices did not do well as a group.

The Y&P U.S. Pharma index increased, but only by 6.0%. The rest fell. The Y&P European Pharma decreased by 14.6%, the Y&P Specialty Pharma index by 20.5% and the Y&P Generic Pharma index by 28.3%. As a result, there was a decline in the public valuations of ethical pharma, generic pharma and specialty pharma companies in the West.

Clouds of uncertainty around the pharma industry were a heavy contributor, such as the U.S. presidential elections and the very visible and damaging pricing controversy.

The industry fared better in the first quarter of 2017. The global equity markets performed modestly well with the S&P 500 increasing by 4.6% and the FTSE 100 increasing by 2.0%. However, three of the four Young & Partners pharma indices performed better than the market. The Y&P U.S. Pharma and European indices did well, increasing by 5.1% and 7.1%, respectively, and the Y&P Specialty Pharma index increased by 6.5%. Only the Y&P Generic Pharma index did poorly, decreasing by 6.7%.

Pharma Equity Financing and M&A

Equity issuance during 2016 was \$16.4 billion of equity issued—versus \$32.7 billion for all of 2015—a drop by about half. Part of the reason was the reduced M&A volume that dampened the need for equity. However, it was also partly due to the volatility of the equity markets and the negative sentiment about the biopharma industry.

There were only eight pharmaceutical IPO's in 2016.

In 2016, 44 M&A deals were completed worth \$120.5 billion, versus 58 deals completed worth \$201.5 billion the year before. These were healthy numbers, but were major decreases from the activity in the previous year in terms of dollars and numbers of deals.

With only two large deals completed, the \$31.0 billion acquisition of Baxalta by Shire and the \$40.4 billion acquisition of Allergan's Generics Business by Teva, there were very few mega deals compared to previous years.

The rationale for deals remained the same, as pharma companies sought to strengthen their product portfolios, replace pending revenue losses from patent expirations, and restructure their business portfolios.

However, the loss of tax inversions as an alternative for U.S. drug companies, the negative publicity around drug pricing, and the political uncertainties associated with the U.S. presidential election all contributed to a dampening of M&A activity.

As of December 31, 2016, the value of the deals announced, but not closed, was \$4.4 billion (15 deals), a very modest number in terms of dollars, but a solid number of deals. In contrast, the pipeline of deals announced, but not closed, at the end of 2015 was \$240.4 billion (16 deals)—but many did not close and the biggest failed deal was the massive Pfizer/Allergan deal.

How has the M&A fared thus far through the first quarter of this year? During the first quarter of 2017, six deals were completed worth \$7.1 billion versus 44 deals completed worth \$120.5 billion in 2016. On an annualized basis, this represents a dramatic decrease in both numbers of transaction and the dollar volume. This is a continuation of a subdued M&A market that, in spite of the need for pharma companies to buy pharma businesses for strategic reasons and to shed non-core assets, is being held down by the same factors that caused the slowdown in the latter part of last year. Additionally, there are some added factors such as the move to replace Obamacare and revise the tax laws (that could both help and hurt M&A activity if corporate tax rates are lowered in the U.S., and the penalty to repatriate overseas cash by U.S. pharma companies is reduced).

As of March 31, 2017, the pipeline of the deals announced, but not closed, had increased from year-end to \$34.7 billion (16 deals), but most of the dollar volume was Johnson & Johnson's proposed acquisition of Actelion.

Biotech Equity Market Performance

As we indicated above, 2016 saw the S&P 500 rise 11.2% from the beginning of the year. The FTSE 100 increased by 17.2%. Most of our biotech indices did poorly. The Y&P Large Cap Biotech index decreased by 14.6%, the Y&P Mid Cap Biotech index decreased by 5.2%, and the Y&P Small Cap Biotech index increased by 10.4% in 2016. Much of the blame was due to the negative publicity around drug pricing.

During the first quarter of 2017, when the S&P 500 increased by 4.6% and the FTSE 100 increased by 2.0%, the Young & Partners Large, Mid and Small Cap Biotech indices performed well, increasing by 5.1%, 15.5% and 21.6%, respectively. This was a welcomed improvement during a period when equity financing was still a challenge.

Biotech Equity Financing and M&A

Equity issuance in 2016 fell significantly with 126 equity offerings worth \$8.7 billion completed—compared to 206 offerings worth \$20.1 billion in 2015. In 2016, only 26 IPOs were completed for a total of \$1.9 billion in new equity, well below 2015 when 61 IPOs were completed, totaling \$5.3 billion. The equity and IPO markets have continued to be tepid for biotech.

Biotech M&A activity has almost always been modest historically, with small spurts of activity from time to time.

In 2016, there were 42 biotech M&A deals completed worth \$19 billion compared to 31 deals worth \$19 billion in 2015, and 28 deals worth \$13 billion in 2014. The number of deals and the dollar volume has increased significantly since 2014. This increase has been fueled by the pharma companies and their need to fill product pipelines and by the financial squeeze facing biotech companies due to the slowdown in IPOs and public secondary offerings.

Sealed off from high valuation equity offerings, the biotech companies have been less fortunate than they were in 2013, 2014, and most of 2015 when they were able to raise money at high valuations. In many cases, the biotech companies have not been able to go public at all. As a result, the biotech organizations in the midst of Phase II and Phase III clinical trials, where the cash consumption is high, have been forced to either sell or to partner in order to deal with their shortage of cash.

However, the pipeline of deals slowed significantly towards the end of last year. Global M&A slowed with increased geopolitical uncertainties around the world and the controversial U.S. presidential elections, but there was added uncertainty surrounding the biotech sector with the U.S. Republican Party's promises to repeal and replace Obamacare, uncertainty around changes in tax laws and rates in the U.S., and the pricing controversies surrounding many companies such as Mylan, Mallinckrodt and the industry as a whole. This slowdown continued in the first quarter of 2017 with only eight biotech M&A deals completed worth \$1.4 billion. This was a significant slowdown on an annualized basis, compared to 2016.

The pipeline of deals announced but not closed as of March 31, 2017 was also weak at only \$600 million (three deals).

Outlook: Pharma

The business outlook for pharma companies will continue to be positive in regard to drug development, with promising drugs in the pipeline. The industry's trajectory in drug development innovation and productivity, directly and indirectly through the biotech industry, is strong and will continue to be strong.

There is some uncertainty about the recent drop in FDA approvals, but activity seems to have picked up and there is a push to ease the approval process in the U.S.

Generic pharma companies will continue to consolidate, cut costs, and push selectively into higher value and more protected product areas.

Ethical and Specialty pharma companies will continue to partner, license, and acquire to maintain the strength of their overall business portfolios and scale, but some companies are under attack due to the drug pricing issue.

The stock market prices and valuations of the ethical pharma industry have suffered with the recent volatility in the overall markets and the controversy over drug pricing that has become a very public issue.

Specialty and Generic Pharma companies have suffered even more with regard to their public company valuations.

It is unclear how long the overall equity markets will be disrupted, but it is our expectation that the negative news will continue to counterbalance the positive news for the biopharma industry. Equity issuance will continue at a modest pace. However, companies will continue to rebalance their balance sheets post larger M&A transactions.

Young & Partners expects M&A activity in 2017 to be moderate, a continuation of the relative weakness experienced in 2016. The general uncertainties affecting the industry will be a factor. In any case, the shutdown of the large inversion deals will continue to block what was previously a flurry of mega deals.

However, number of deals will still be significant, driven by restructuring and strategic needs of the pharma companies and the residual impact of what was a feeding frenzy.

Pharma companies will continue to acquire to enhance their product pipelines and strategic thrusts, while selling off non-core businesses.

The need to fill the shrinking drug pipeline will also fuel in-licensing arrangements, partnerships and joint ventures with biotech companies and other pharma companies.

Outlook: Biotech

The development capabilities of biotech companies have been and will continue to be positive overall. Although there will be successes and failures by individual companies, biotech companies have demonstrated their ability to develop new drugs at a faster pace than the larger pharma companies.

The stock market favored biotech companies for a number of years. This changed in the second half of 2015 for a number of reasons, including the negative stories around drug pricing.

It is hard to predict whether and when the current depressed biotech equity market will recover to more attractive levels.

However, we do not see a near-term recovery in the equity issuance market, particularly for IPOs, as long as the uncertainties about the industry and the negative public view of the industry continues.

Biotech companies will have to turn more to partnering, licensing and M&A for funding and shareholder liquidity.

The primary biotech M&A theme has been pharma and big biotech acquisitions of biotech companies for pipeline enhancement.

The most promising biotech companies over the previous three years were able to go public first and attract significant interest and high prices later. However, the recent slowdown in IPOs has driven many companies to either sell themselves or raise funds via partnering deals and/or discounted private placements, and we believe this will continue for some time.

Therefore, M&A volume and partnering deals will be active in 2017 and beyond, but well below the level of the pharma industry, as has been true for many years.

Implications for senior management

For ethical pharma companies, there will continue to be a wide variety of tools to acquire revenues and pipeline drugs, but the valuations are challenging, particularly for promising drugs in late stage clinical trials and for companies with strong products.

The challenge will be to pick the right overall mix of M&A, licensing, and partnering to accomplish corporate strategic goals and defend and deliver shareholder value.

The generic pharma companies will continue to face a number of industry challenges. This will result in a continuation of the current industry consolidation and selective strategies around diversification.

For biotech companies, public and private, the future is exciting from the drug development side, but troubling on the private funding, IPO, secondary equity financing, and M&A fronts.

Time will tell whether the very public attack on drug pricing and the likely changes in the U.S. healthcare insurance and tax regulations will force changes in the industry.

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