Pharma and Biotech Markets

Peter Young

Mostly sunny, but challenging to forecast

For most of the last 10 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, which was troubling, but now appears to have been 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 cooled off in the second half of 2015 and plunged in 2016. Secondary offerings were strong in 2015, but also fell precipitously in 2016. This created a difficult equity financing environment for biotech companies, which, in turn, limited the choices available to biotech firms to continue to fund their companies. This contributed to a surge in M&A activity in 2015 and 2016 as many biotech companies 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 half of 2017 and what we expect for the rest of the year and beyond. We will also share our view of 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 increase 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 to the decline, such as the negative comments about the industry during the U.S. presidential elections and the very visible and damaging pricing controversy.

The industry fared better in the first half of 2017. The global equity markets performed moderately well, with the S&P 500 increasing 7.3% and the FTSE 100 by 1.9%. This time, the Y&P U.S. Pharma and European indices did better than the market, increasing by 8.5% and 14.6%, respectively. The Y&P Specialty Pharma index also increased, but only by 4.6%.

Only the Y&P Generic Pharma index did poorly, decreasing by 4.3%.The poor performance by the generic companies has been driven by their difficulties getting new volume and by intense pricing pressure.

Pharma equity financing and M&A

Equity issuance during 2016 equaled $16.4 billion 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 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. During 2016, 44 M&A deals were completed worth $120.5 billion versus 58 deals completed worth $201.5 billion in 2015. Although these were healthy numbers, they were a major decline from 2015.

Part of the problem was the sparsity of mega deals. Only two large deals were completed, the $31.0 billion acquisition of Baxalta by Shire and the $40.4 billion acquisition of Allergan's Generics Business by Teva.

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

So why the dampening of M&A activity? Three of the principal reasons were 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 elections where the drug industry was a target of all of the candidates.

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 of those deals did not close and the biggest failed deal was the massive Pfizer attempt to acquire Allergan.

How has the M&A market fared thus far through the first half of this year? During the first half of 2017, only 13 deals were completed worth $42.2 billion versus 44 deals completed worth $120.5 billion for all of 2016. The majority of this dollar volume was Johnson & Johnson's acquisition of Actelion. On an annualized basis, this was a dramatic decrease in both the number of transactions and the total dollar volume and a continuation of the slowdown that started last year.

Further, as of June 30, 2017, the pipeline of the deals announced but not closed was only $9.2 billion (12 deals).

Biotech equity market performance

As we indicated above, 2016 saw the S&P 500 up 11.2% from the beginning of the year and the FTSE 100 up 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.

This year we are seeing a major turnaround. During the first half of 2017 the global equity markets performed modestly well, but the Young & Partners Large, Mid, and Small Cap Biotech indices performed even better, increasing by 12.1%, 24.6%, and 50.6%, respectively. This was a welcomed improvement over the poor performance overall in 2016.

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 IPO market was frozen for all but the strongest IPO candidates.

On the bright side, equity issuance in first half of 2017 totaled 95 offerings worth $8.4 billion. This was a significant pick-up in pace on an annualized basis compared to the 124 offerings worth $8.7 billion completed in 2016. Although still less than the peak volumes in 2015, it was a vast improvement over the severe slump in 2016.

On the IPO front, the recent news is partially positive. In the first half of 2017, 20 IPOs were completed for a total of $1.5 billion. On an annualized basis, this is well above the weak 2016 (26 IPOs totaling $1.9 billion were completed during the entire year). We are not experiencing the frothy IPO environments of 2014 and the first three quarters of 2015, but we have pulled partially out of the 2016 slump. This has provided relief for some of the private biotech companies struggling to raise funds.

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 increased significantly. 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 were less fortunate in 2016 compared to the period from 2013 through the first half of 2015 when they were able to raise money at high valuations. In many cases, the biotech companies were not able to go public at all. As a result, in 2016 the biotech organizations who were in the midst of high-cash consuming Phase II and Phase III clinical trials, were 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. There was a major increase in geopolitical uncertainties related to the biotech sector. The U.S. Republican Party's repeated vow to repeal and replace Obamacare, uncertainties around potential 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 all contributed to a slowdown in M&A activity.

This slowdown continued in the first half of 2017, with only 16 biotech M&A deals completed worth a mere $2.8 billion. The two largest deals were the acquisitions of CoLucid and Ogeda. This was a major slowdown on an annualized basis compared to 2016 when, as mentioned before, 41 deals worth $19 billion were completed. The 2016 totals were driven by six deals that exceeded $1 billion in value.

Not surprisingly, the pipeline of biotech deals as of June 30, 2017 was extremely weak at only $0.9 billion (five deals).

Outlook: Pharma

The business outlook for pharma companies will continue to be positive in terms of 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 was some concern about the drop in FDA approvals last year, but activity picked up considerably in the first half of 2017 and there is a push to ease the FDA approval process in the U.S. In addition, the FDA announced in late June that it plans to promote drug competition, including expediting the reviews for generic drug applications. This will be helpful to the generic drug companies, but potentially harmful for the ethical pharmaceutical companies.

Pharma companies will continue to adjust their business models and strategies as the environment around them changes and new technologies are discovered. We fully expect big pharma to continue to pursue radical structural changes to shift the nature and quality of their business portfolios.

Specialty pharma companies will partner, license, and acquire to maintain the strength of their overall business portfolios and scale. However, many of these companies are under attack around the drug pricing issue and some are finding that their orphan drug strategies have limitations in terms of insurance company reimbursement policies.

Young & Partners expects Pharma M&A activity for the rest of 2017 and beyond to be relatively weak, a continuation of the relative weakness experienced in 2016. The shutdown of the large inversion deals has been and will be contributed to the dollar slowdown. However, volume 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, but that sentiment weakened starting in the second half of 2015 with a number of negative stories hitting the biopharma industry around pricing and other issues, impacting the IPO and secondary equity issuance volume.

We expect the recent moderate improvement in the stock market and equity issuance market to continue for the biotech industry with positive regulatory changes being discussed. This will help the stronger biotech companies raise equity capital, but we do not expect a near-term return to the frenzy of 2014 and 2015.

However, the biotech M&A market will continue to be subdued, even with the ongoing Pharma interest in building their drug pipelines. This is partly because partnering is an active alternative to M&A and partly because the equity issuance market has improved so that biotechs are not as desperate for cash...

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.

For biotech companies, public and private, the future is exciting from the drug development side in terms of the drug approval environment and innovation, but mixed with regard to private funding, IPOs, secondary equity financings, and M&A fronts.

The key for biotechs will be to properly assess their cash flow requirements and to create and execute a flexible financing/M&A plan that properly assesses how much capital and at what price the various alternatives will give you, whether it is private placements, partnering, IPOs and secondary offerings, royalty monetizations, or sources of non-dilutive financing.

Peter Young is President and Managing Director of Young & Partners, the Life Science and Chemicals Investment Banking firm, and a member of *Pharmaceutical Executive's* Editorial Advisory Board. He can be reached at 212-682-5555 or pyoung@youngandpartners.com.