Pharma and Biotech: Strategic, M&A and Financial Yearend Review and Outlook

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2017 and the last couple of years have been somewhat of a roller coaster ride for the biopharma industry.

There have been a number of very positive developments. 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. Time will tell if the actual results match the intent.

However, there have been times when heavy clouds have appeared in terms of biopharma stock market volatility, access to private and public capital, pricing controversies, geopolitical challenges, and uncertainties around the ongoing regulatory structural changes in a number of the major markets such as the U.S. and China.

The rest of this article will look at what happened from an M&A, stock market and financing point of view and what we expect in the future. We will comment on the implications of these trends for senior executives and investor decisions 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 stock market overall rallied strongly, fueled by optimism about global growth and corporate earnings, and in spite of serious geopolitical tensions.

During 2017 the global equity markets performed well, with the S&P 500 increasing 18.4% and the FTSE 100 increasing by 7.1%.

The performance of the pharma and biotech industries varied dramatically by company type and sector. The Y&P U.S. Pharma and European indices did equally well or better, increasing by 17.3%

and 17.1%, respectively. The Y&P Specialty Pharma index, however, decreased by 10.4% as many of the companies have come under attack for price increases for older drugs and for newer orphan drugs. The Y&P Generic Pharma index decreased by 10.9% for a different set of reasons. The generic drug companies are suffering as the number of drugs coming off patent has slowed and the level of competition in generics has increased many fold.

Pharma Equity Financing and M&A

Equity issuance in 2017 was a mere $7.7 billion versus $16.4 billion for all of 2016, a dramatic decline on an annualized basis.

In addition, there were only 12 pharmaceutical IPOs in 2017. There are generally very few IPOs in pharmaceuticals, so this is not a change from the past.

In 2017, only 23 deals were completed worth $42.1 billion versus 45 deals completed worth $119.3 billion in 2016. This was dramatic decrease in both the number of transactions and the total dollar volume.

This decrease in M&A activity was a reflection of the great uncertainties facing the industry around pricing and regulation and the loss of the tax inversion driven deals. The drop was not due to any reduced desire to grow or to enhance business portfolios.

Clearly there was a sparsity of mega deals. There was only one mega deal, J&J's acquisition of Actelion for $29.2 billion. The next largest deal was only $5 billion in size.

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 new and unknown policies of the new administration in the U.S.

As of December 31, 2017, the pipeline of the deals announced but not closed was only $19.6 billion (12 deals), an indication that in the near-term we will be operating at a level that is slightly higher than 2017, but not at record levels. The recently announced acquisition of Bioveritiu by Sanofi for $11.4 billion may be a sign of a pick-up in M&A activity.

Biotech Equity Market Performance

On the biotech stock market front, the Y&P Mid and Small Cap Biotech indices performed exceptionally well, increasing by 23.2% and 37.4%, respectively. The Y&P Large Cap Biotech index, however, did not perform as well, increasing by a solid but less spectacular 9.5% during 2017.

This was a welcomed improvement over the poor performance overall in 2016.

This was driven by the strong overall stock market and by indications by senior Washington officials that the FDA drug approval process will accelerate. However, this was partially off-set by the negative impact of the drug pricing issue and signs that orphan drugs will not get a free ride with regard to pricing.

Biotech Equity Financing and M&A

Equity issuance (secondary and IPO) in 2017 totaled 205 offerings worth $21.1 billion. This was a record dollar amount and a record number of issuances and a significant pick-up in pace compared to the 124 offerings worth $8.7 billion completed in 2016.

There was a partial rebound in the biotech IPO issuance market. 45 IPOs were completed in 2017 for a total of $4.0 billion. This is well above the weak 2016 when only 26 IPOs totaling $2.4 billion were completed. For those companies who struggled to complete IPOs in 2016, it was a partial improvement, but still well below the levels in 2014 and 2015.

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

This trend continued in the 2017, with only 23 biotech M&A deals completed worth only $14.9 billion. The acquisition of Kite by Gilead dominated with a value of $10.1 billion of the total. That meant that the remaining 22 deals totaled just $4.8 billion.

This was a significant slowdown on an annualized basis compared to 2016 when 41 deals worth $20 billion were completed, driven by six deals that exceeded $1 billion in value. This mirrors the slowdown in the pharma M&A market.

Although the pipeline of biotech deals as of December 31, 2017 was modest at only $4.1 billion (8 deals), there has been a flurry of recently announced large biotech deals such as Novo Nordisk’s €2.6 billion offer (since rejected) to buy biotech Ablynx and Celgene’s deals to buy CAR-T therapy company Juno Therapeutics for $10.3 billion and cancer drug maker Impact Biomedicines for $1.1 billion up front and a potential $1.25 billion extra depending on performance.

Outlook: Pharma

Business

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 in 2016 to only 22 approvals, but activity picked up considerably in 2017 to 44 approvals 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 expedited reviews of 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 structural changes to shift the nature and quality of their business portfolios.

Generic pharma companies will continue to consolidate, cut costs, and push selectively into higher value and more protected product areas. They are and will continue to be under intense pricing and competitive pressures.

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 severe attack around the drug pricing issue and some are finding that their orphan drug strategies have limitations in terms of insurance company reimbursement policies.

Equity Markets

The stock market prices and valuations of the Ethical Pharma industry suffered for some time, but rebounded nicely in 2017. We expect that to continue in 2018 as long as the overall stock market performs well.

Specialty and Generic Pharma company stock prices have suffered heavily due to industry pricing issues and competition and will continue to be under pressure in 2018. It is our expectation that the negative news will continue to counterbalance the positive news for these two sectors of the biopharma industry.

M&A

Young & Partners expects M&A activity in 2018 to see a major uptick as the recent overhaul to the US tax code reduces R&D credits but lowers the penalty for repatriating cash, encouraging pharma companies to buy rather than build. Volume will also be driven by the restructuring and strategic needs of the pharma companies as they 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

Business

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. There is also the hope that novel drugs and arrangements with payers will allow biopharma companies to achieve attractive and sustainable pricing.

Equity Markets

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 the 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.

M&A

Although the pipeline of deals announced but not closed at the end of 2017 was relatively modest, we believe that were will be a significant pick-up in the biotech M&A market this year.

With the ability to repatriate cash at reduced tax rates for U.S. companies, the ongoing successes of biotech companies in their drug development programs, and the validation of a number of new technologies, pharma companies will likely become more aggressive in their pursuit of biotech company acquisitions.

However, their interest will be focused on specific targets in favored therapeutic and technology areas and on biotechs that have made significant clinical progress.

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 will continue to be challenging, particularly for companies with promising drugs in late stage clinical trials or FDA approval. 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 the Specialty Pharma companies, the key will be a rethinking of their strategies since it is not clear that the pursuit of niche and orphan drug markets will continue to bear fruit in the same way that they have in the past. The high price of acquisitions and the pressure on drug pricing even for orphan drugs will have a disproportionate impact on Specialty Pharma companies.

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. The CEOs of the generic pharma companies must be prepared to shift to very different strategies to survive and to thrive.

For biotech companies, public and private, the future is exciting from the drug development side in terms of the drug approval environment and innovation and the improvement that they have seen in the IPO, secondary equity financing, and M&A markets. Unfortunately, the markets have been volatile and have played favorites with regard to therapies, technologies, and stages of development.

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

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