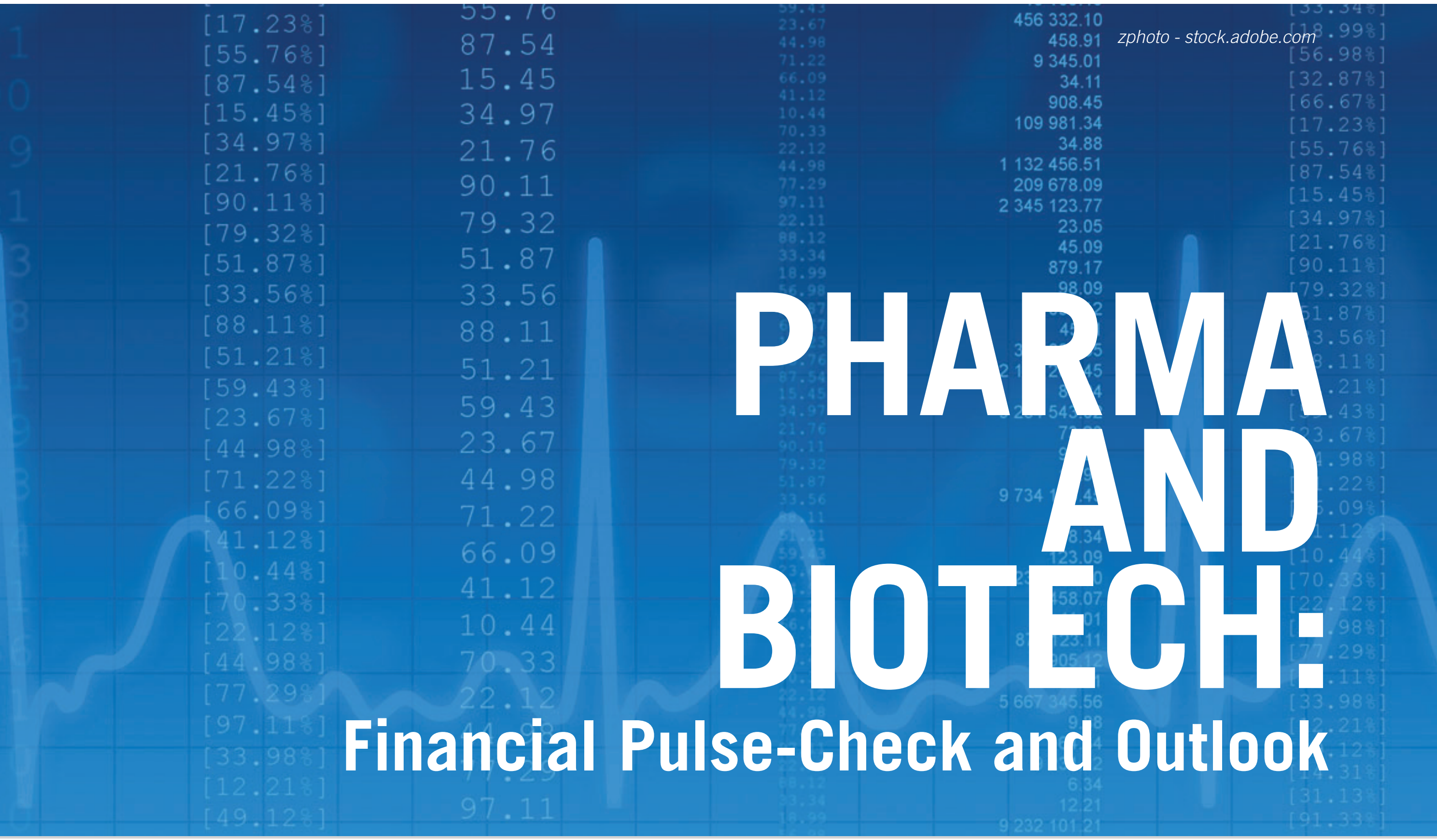
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PHARMA AND BIOTECH:

Financial Pulse-Check and Outlook

A review of market performance and trends in 2018 and first quarter of 2019 for the life sciences industry

By Peter Young

It has been an exciting and a challenging year so far for the pharmaceutical and biotechnology industries. On the positive side, the number of new drugs approved and under development has increased for pharma and biotech companies. Big pharma development productivity was weak for a number of years, but has visibly improved at many pharma organizations. Several of the large pharma manufacturers have adjusted their approach to development. Biotech companies, as a group, continue to demonstrate their positive drug development capabilities.

The emergence of a host of new therapeutic methods, such as immuno-oncology, CRISPR, personalized medicine, and stem cells has been exciting, albeit with the normal periodic setbacks such as the one we are seeing in CRISPR. In addition, there have been many proposed and implemented changes in US FDA and Chinese FDA policies with regard to drug approvals that are favorable. Time will tell if the actual results match the intent.

This article reviews market performance results and developments through year-end 2018 and the first quarter of 2019. As we will document, biotech companies have been able to raise considerable equity capital through private placements, IPOs, and secondary public offerings.

But the challenges are also visible as well. For pharma companies, the hurdles continue to include low sales growth relative to history, the high cost of drug development, controversies around pricing, the scrutiny of orphan drug pricing, lower profitability relative to history, increasing price and formulary pressure from payers, weak pricing leverage outside the US, and structural changes in healthcare and government policies in large countries such as the US and China that are impacting pharma. Biotech companies are facing some of the same challenges.

This article will also look at what happened from an M&A, stock market, and financing perspective in 2018 and the first quarter of this year and what we expect in the future. We will also comment on the implications of these trends for senior executives and investor decisions in the pharma and biotech industries.

Pharma equity market performance

During 2018, the US equity markets did poorly, with the S&P 500 decreasing 7%, while European markets fared worse, with the FTSE 100 dropping by 12%. Most of the Young & Partners (Y&P) pharma indices also did poorly, heavily influenced by the overall market.

The Y&P US Pharma index increased by 10.2%, while the European Pharma index decreased by 1.2%. The Y&P Generic Pharma index did poorly, dropping by 23%, driven by a decline in patent expirations, an increase in low-cost competitors from India and China, and declining product prices. The Y&P Specialty Pharma index decreased by 3.6%.

Fortunately, there was a rebound in the overall markets and many of the pharma indices in the first quarter of 2019. US equity markets did well, with the S&P 500 increasing 12.9%. The European markets were also solid, with the FTSE 100 jumping 8.1%.

There was a big difference in the US and European Pharma stock market performance. The Y&P US Pharma index increased by 4.4% while the European Pharma index grew by 12%.

The Y&P Generic Pharma index also performed well, increasing by 6.1%, and the Y&P Specialty Pharma index was up 18.1%—both rebounding from significant declines in 2018.

Pharma equity financing and M&A

Equity issuance in pharma has always been modest relative to the size of the industry. Equity issuances in 2018 totaled $11.3 billion, versus $7.6 billion for all of 2017, a significant increase. In addition, there were 13 pharmaceutical IPOs last year. Equity issuances in the first quarter of 2019 totaled $5 billion, a meaningful increase versus $3.5 billion in the first quarter of 2018.

On the M&A front, 25 deals were completed last year worth $26.4 billion, compared to 24 completed for $47 billion in 2017. This was a significant decrease in dollar volume, but the number of deals held up. In either case, however, when measured against long-term historical numbers, these levels are relatively modest.

As of Dec. 31, 2018, the pipeline of the deals announced but had not yet closed was $87.9 billion, with the since-finalized Takeda acquisition of Shire accounting for most of the total.

In the first quarter of this year, five M&As were completed worth $66.8 billion, versus four deals completed worth $13.4 billion in the first quarter of 2018 and the 25 for $26.4 billion in all of 2018. The Takeda-Shire merger accounted for $62 billion of that amount, so the rest of the market saw only $4.8 billion and four deals. Without that mega deal, the first quarter of 2019 fell far short of the first quarter of 2018 in M&A volume and, on an annualized basis, with last year's full-year numbers.

As of March 31, the pipeline of the deals announced but not closed was $104.9 billion (five deals), with the Bristol-Myers Squibb acquisition of Celgene accounting for $74 billion of the total. So, again, a mega deal is dominating the totals for the M&A market going forward.

Why the overall slowdown during these periods (although, it should be noted that activity picked up in the second quarter with AbbVie's announced $63 billion acquisition of Allergan and Pfizer's purchase of Array BioPharma for $11.4 billion)? It is partly due to several uncertainties facing the industry, but also due to a resurgence in the R&D productivity of many pharma companies, their recognition that past mega mergers did not accomplish much other than cost synergies, and a flood of biotech partnering and M&A transactions. The Takeda acquisition of Shire is different because it is a major geographic move on Takeda's part, so that it will be less dependent on the Japanese market.

> There was a rebound in the overall markets and many of the pharma indices in the first quarter

Biotech equity market performance

During 2018, the US equity markets did poorly, with the S&P 500 decreasing 7%, while European markets fared worse, with the FTSE 100 dropping 12%.

The Y&P Large and Mid Cap Biotech indices also performed poorly, decreasing by 7.2% and 18.6%, respectively. Only the Small Cap Biotech index performed well, growing by 24.2%.

The significant uncertainties around the macro trends in the biotech industry contributed to the overall weakness of biotech stock market prices.

The stock market staged a dramatic recovery in the first quarter of 2019, with the S&P 500 increasing 12.9% and the FTSE 100 by 8.1%.

The Y&P Large and Mid Cap and Small Cap Biotech indices also performed well, increasing by 10%, 32.6%, and 23.8%, respectively.

The biotech share prices are being buffeted by the negative publicity about drug pricing, some initial payer pushback against orphan drug pricing, and the ongoing struggle to fund research and clinical trials in a volatile private funding and public equity market.

Biotech equity financing and M&A

Equity issuance (secondary and IPO) in 2018 totaled 250 offerings worth $26.6 billion, a record deal count and dollar amount. Of those, 68 were IPOs worth $7.4 billion, a surge over the 44 completed totaling $3.9 billion in the previous year. This was not a record number of IPOs compared to the 74 in 2014, but it was by far the record dollar amount.

The equity financings continued at a strong, but lower level in the first quarter of this year. Equity issuance (secondary and IPO) totaled 46 offerings worth $5.5 billion, versus 69 offerings worth $7.3 billion in the first quarter of 2018 and 250 offerings worth $23.7 billion completed for all of 2018. Ten of those equity offerings were IPOs worth $1.4 billion.

Biotech M&A activity has almost always been modest historically, with small spurts of activity from time to time. Last year saw a record dollar volume of $35.4 billion from 35 biotech M&A deals completed. This was a significant increase compared to 2017, when 25 deals worth $15.4 billion were completed.

In first quarter 2019, M&A volume was four deals worth $7.4 billion completed, versus seven deals worth $13.1 billion in the first quarter of 2018. However, one deal dominated: the acquisition of Loxo Oncology by Eli Lilly for $7.2 billion. This was a significant decrease on an annualized basis compared to 2018, when 35 deals worth $35.4 billion were completed. So the M&A market has slowed significantly.

The dollar value of the pipeline of deals as of March 31, 2019 was also very modest at $2.5 billion (five deals).

The modest M&A volume is understandable as the strong IPO and secondary equity issuance markets have allowed biotech companies to raise capital and avoid an early sale to a strategic pharma company. But, more importantly, the ongoing use of partnering, out-licensing, non-dilutive research grants, and other vehicles create opportunities to collaborate without selling the company or to get funding that allows the biotech to build shareholder value as an independent company.

Outlook: Pharma

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

Pharma organizations are pursuing new business models and strategies with a range of successes and failures.

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

Specialty pharma has been partnering, in-licensing, and acquiring to maintain growth and the strength of their overall business portfolios, but the business models of many of these companies are failing.

Equity markets. The stock market prices and valuations of the ethical pharma industry companies have weakened as the negative pressures on the industry remain, in spite of a mixture of R&D and commercial successes. It is our expectation that the negative news will continue to counterbalance the positive news for the biopharma industry.

Specialty and generic pharma company share prices will continue to suffer as these organizations deal with serious business issues/pressures.

Equity financing. We expect the equity financing market for pharma to be modest, but very healthy. The pharma industry tends not to raise new equity very often unless an individual company has to raise equity to repair its balance sheet after an acquisition.

M&A. Young & Partners expects M&A activity, with the exception of a handful of mega deals, to continue to be modest for the reasons mentioned. Mega deals that merge existing mature biopharma companies are no longer being pursued as CEOs and boards recognized that cost synergies alone are not long-term creators of value. Hence, large deals have either a strategic rationale or a theme around adding new and growing technologies and products. On the other hand, the need to fill the shrinking drug pipeline will also fuel in-licensing arrangements, partnerships, and joint ventures with biotech companies and other pharmas.

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, biotechs 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 organizations to achieve attractive and sustainable pricing.

Equity markets. The stock market performance of biotech companies was volatile and strong in the first quarter of 2019, except for the large-cap companies. We believe the volatility will continue this year, with fluctuations driven by the likely volatile industry news.

Equity financing. Biotech companies will continue to tap the equity markets, partnering, licensing, and royalty monetization for funding and for shareholder liquidity.

Secondary equity offerings have been exceptionally strong and will continue to be strong and IPOs will also perform well as long as the overall stock market environment is positive.

M&A. Although the pipeline of deals announced but not closed at the end of the first quarter was relatively modest, we believe that the industry will end up with a moderate volume of biotech M&A activity this year.

However, the buyer 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 M&A valuations will remain challenging, particularly for companies with promising drugs in late-stage clinical trials or in 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 specialty pharma organizations, 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.

Generic pharma companies will face a number of remaining industry challenges. This will result in a continuation of the current industry consolidation and selective strategies around diversification. The CEOs of generic drugmakers must be prepared to shift to very different strategies to survive and to thrive.

> Biotechs will continue to tap the equity markets, partnering, licensing, and royalty monetization

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. However, prosperity or disappointment will vary by the story of each company. Unfortunately, the markets have been volatile and have played favorites with regard to therapies, technologies, and stages of development.

The key for biotech organizations 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 cost of equity the various alternatives will provide, whether it is private placements, partnering, IPOs and secondary offerings, royalty monetizations, or sources of non-dilutive financing.

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