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BUSINESS CHECK
INDUSTRY'S FINANCIAL PULSE

INNOVATION CULTURE
CAN IT STUNT R&D?

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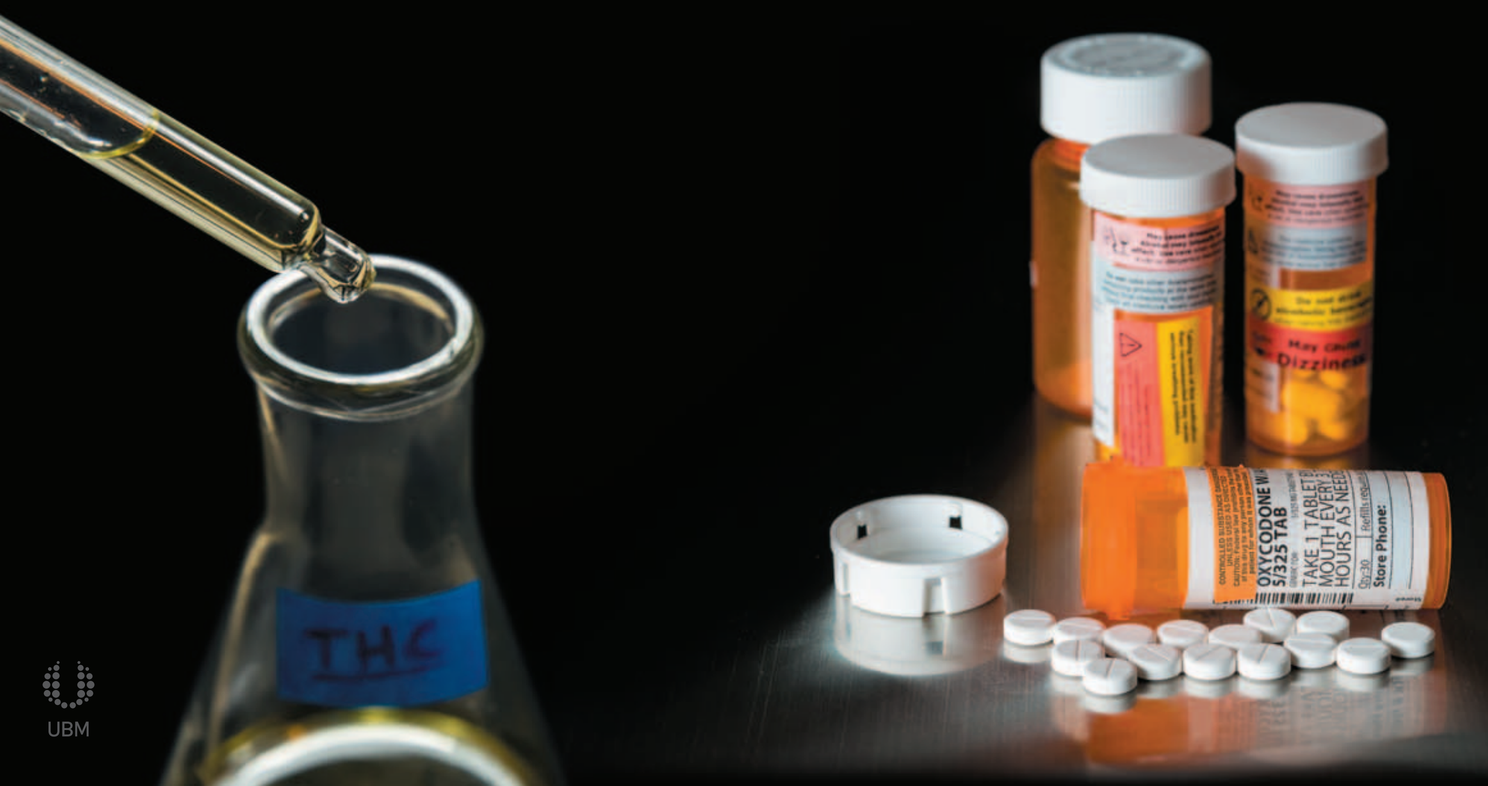

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Biopharma Business Check

Opportunities and obstacles have characterized 2018 to date

The increase in new drug approvals and candidates in development are good signs for pharma and biotech, but both sectors face continued pricing, cost, and healthcare policy-related challenges ahead

By Peter Young

2018 has turned out to be an exciting and challenging year for the pharmaceutical and biotechnology industries.

On the positive side, the number of new drugs approved and under development has escalated for both pharma and biotech companies. Pharma development productivity was weak for a number of years, but there has been a very visible increase in clinical success for a number, but not all, of the large pharma companies as they have adjusted their approach to development. Biotechs, as a group, continue to demonstrate their positive drug development capabilities.

The emergence of a host of new methods, such as immuno-oncology, CRISPR, personalized medicine, and stem cells has been promising, 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.

As we will document in this article, biotech companies have been able to raise considerable equity capital through private placements, IPOs, and secondary public offerings. There has never been such a long period when the IPO window has been open for biotech companies as we have seen for a number of years now.

But the challenges are also visible as well. For the pharma companies, the challenges 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.

The rest of this article will look at what happened from an M&A, stock market, and financing point of view through the third quarter of 2018 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 the first three quarters of 2018 the US equity markets were robust, with the S&P 500 increasing 8.1% while European markets were tepid, with the FTSE 100 decreasing by 1.8%.

The performance of the pharma and biotech industries varied dramatically by geographic region, company type, and sector.

The Y&P US Pharma index did well, increasing by 11.1%, while the European Pharma index was nearly flat, decreasing by 0.5%. The weaker European index performance was heavily influenced by the weak European stock market due to a variety of issues such as Brexit and the problems in certain countries such as Italy.

The Y&P Generic Pharma index also did poorly, decreasing by 5.5%, driven by accelerated abbreviated new drug application (ANDA) approval times, an increase in low-cost competitors from India and China, and hurdles to raising prices.

In contrast, the Y&P Specialty Pharma index did well, increasing by 17.8%, after a disastrous 2017. This improvement was not so much because the sector did well as it was a recovery from very negative sector events last year.

Pharma equity financing and M&A

Equity issuance in pharma has always been modest relative to the size of the industry. In the first three quarters of 2018, $18 billion was raised, versus $7.6 billion for all of 2017, a very significant increase on an annualized basis. In addition, during the same three quarters there were 11 pharmaceutical IPOs.

On the M&A front, during the first three quarters of this year, only 12 deals were completed worth $18 billion, versus 23 deals completed worth $42.1 billion in 2017. On an annualized basis, this was a dramatic decrease in terms of the number of transactions and dollar volume. Compared to many years of historical data, this level is also relatively modest.

As of September 30, 2018, the pipeline of the deals announced but not closed was $93.9 billion (11 deals), with the Takeda acquisition of Shire dominating, accounting for $81.7 billion of the total. The Shire deal aside, the pipeline was only $12.2 billion.

Why the slowdown? It is partly due to a number of uncertainties facing the industry, but it is also due to a resurgence in the R&D productivity of many pharma companies, their recognition that the mega mergers did not accomplish much other than cost synergies, and a flood of biotech partnering and M&A transactions. The Takeda-Shire combo is a bit different because it is a major geographic move on the part of Takeda so that it will be less dependent on the Japanese market. The deal is still under antitrust review in the EU, so whether it goes through and when is not yet clear.

Biotech equity market performance

The performance of biotech shares were positive across the board during the first three quarters of this year. The Y&P Large, Mid, and Small Cap Biotech indices performed well, increasing by 7%, 19.4%, and 47.8%, respectively. This was a continuation of the positive performance of the sector last year.

Although part of the positive showing was driven by the strong overall stock market, other factors were the solid business performance of many biotech companies, the emergence of new technologies, and indications by senior Washington officials that the FDA drug approval process is going to be accelerated. These positive trends were partially offset 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

Biotech equity issuance in the first three quarters of 2018 totaled 200 offerings worth $21.7 billion. On an annualized basis, it is on a pace to shatter the record dollar amount and number of issuances set in 2017, when $21.1 billion was issued from 204 offerings.

Fifty IPOs were completed in the first three quarters, valued at $4.9 billion. This number is already greater than the totals for 2017, when 44 IPOs equaling $3.9 billion were completed, and on an annualized basis is approaching the 2014 record of 72 IPOs that raised $5.7 billion.

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

However, the first three quarters of this year saw a record dollar volume of $31.4 billion, based on the value of the 24 biotech M&A deals completed. The number and the dollar value of biotech deals have gone up considerably. This was a significant increase on an annualized basis compared to 2017, when 24 deals worth $15.1 billion were completed.

The increase has been driven by the strong demand for new drug products by pharma companies. It is somewhat unusual in that biotech M&A is often weaker when the biotech IPO market is strong and biotech companies can postpone a sale of the company until further progress has been made. Obviously, the large pharma firms are willing to pay up to get at certain therapeutic areas, technologies, and pipelines.

The three largest deals were Celgene's acquisition of Juno Therapeutics for $10 billion, Novartis' purchase of AveXis for $8.1 billion, and Sanofi's acquisition of Ablynx NV for $4.1 billion.

The dollar value of the pipeline of deals as of September 30, was solid, but not spectacular at $3.5 billion (six deals).

Outlook: Pharma

Business. The business outlook for pharma companies is positive overall, but is a mixture of positives and negatives.

With regard to drug development, many pharma companies have promising, innovative drugs in their pipeline. The industry's trajectory with regard to drug development and productivity has been improving, both in-house and indirectly through the biotech industry.

However, there are many industry uncertainties that are evolving with regard to pricing, industry structure, the lower value of big pharma's sales forces and distribution to the biotechs pursuing orphan drugs, and ongoing patent expirations.

Generic pharma companies are under severe profit pressures and will continue to consolidate through mergers, 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 will continue to do well in the US, but with mixed results in Europe. The specialty and generic pharma company share prices will continue to suffer as these companies deal with serious business issues/pressures. It is our expectation that the negative news will continue to counterbalance the positive news for these two sectors of the biopharma industry.

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 their balance sheet after an acquisition.

M&A. Young & Partners expects M&A activity to continue to be subdued for the reasons mentioned. At the same time, the need to fill the shrinking drug pipeline will also fuel in-licensing arrangements, partnerships, and joint ventures with biotechs 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 organizations have demonstrated their ability to develop new drugs at a faster pace than the larger pharma firms. 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 performance of biotechs has been volatile, but has been positive overall due to industry dynamics and a strong stock market. Overall performance will continue to be positive, driven by the net positive view of the biotech industry and its ability to produce new drugs.

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

M&A. We believe that the biotech M&A market will continue to be strong both in terms of the numbers of deals and the dollar volume for the rest of this year and into next year. We expect the need for new drug candidates and revenues will drive pharma organizations to pursue biotech company acquisitions, in spite of the lofty valuations and the easy access to capital that the biotechs are enjoying currently.

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

Implications for senior management

For ethical pharma firms, there will continue to be a wide variety of tools to acquire revenues and pipeline drugs, but the 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 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.

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 generic drugmakers 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 approval environment and innovation and the improvement 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 companies 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. PE

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