Doubling Down On Innovation, Recovery

Though M&A activity and equity market outputs have been mixed, and pandemic challenges linger on, the outlooks for pharma and biotech remain stable—driven by R&D gains, record IPO levels

PETER YOUNG
is CEO and President of Young & Partners, and a member of *Pharm Exec*'s Editorial Advisory Board.
He can be reached at
pyoung@youngandpartners.com

Not that long ago, the overall mood in the pharmaceutical and biotechnology industries was somewhat gloomy. The public image of the industry had fallen from being one of the most respected to being characterized as the greedy villain behind high drug prices. Innovation by the large pharma companies had slowed dramatically, even with a slew of innovations focused on speeding up the drug discovery process and on new technologies. The stock market valuations had relentlessly fallen and IPOs of biotech companies were few and far between.

Dialing forward to the picture over the last two years or so and the situation is far more positive. A flurry of new and innovative drugs has shown a global audience that the biopharma industry serves a critical role in fighting diseases. This has been highlighted by new, high-profile discoveries and effective solutions to the current coronavirus crisis, whether it is vaccines or drugs that reduce the severity of the disease for those who are infected. The hugely important development of vaccines to combat COVID-19 has saved millions of lives and, at the same time, changed the attitude of the general public in a more positive direction. Innovation has exploded in all parts of the ecosystem: large pharma, biotech, and collaborations between large pharma and biotech companies, research organizations, and universities. Many of the innovations have been revolutionary (mRNA, immuno-oncology, CRISPR, stem cells, etc.) and others have been evolutionary advances. Drugs and drug delivery systems are being approved in numbers that are very strong. The shift into orphan drugs has created opportunities for biopharma companies of all sizes and has changed the relationship between biotechs and big pharma. Funding for biotech organizations via private investors and institutions and the public markets has been robust, including record numbers of IPOs.

These factors and other structural changes have had a major impact on the strategies of all of the companies in the biopharma ecosystem and have impacted the texture of the M&A, financing, strategic partnering and licensing, and other strategic/financial parameters of the industry.

As exciting as the positive developments have been, the industry, and certainly specific segments of the industry, still face some very significant challenges now and going forward. Generic and specialty pharma companies are struggling to reestablish a winning formula for growth and profitability. The pandemic has had a significant impact on the availability of many drugs, has disrupted supply chains, and constrained the ability to conduct clinical trials when so many people have been sheltering at home and hospitals have been forced to devote their resources to treat COVID-19 patients and less on clinical trial activities and research. Other challenges include the high cost of drug development, continuing controversies around pricing, the scrutiny of orphan-drug pricing, 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 companies.

The rest of this article will look at what happened from an M&A, stock market and financing point of view in 2020 and the first half of 2021 and what we expect for the rest of the year and beyond. We will also comment on the implications of these trends for senior executives and investor decisions in the pharma and biotech sectors.

PHARMA EQUITY MARKET PERFORMANCE

During the first half of 2021, global Western equity markets surged as excess funds flowed into the Western equity markets and there were positive economic signs in the US, China, and, to a certain extent, the European Union.

By the end of the first half, the S&P 500 had increased dramatically by 16.1% and the S&P Euro 350 had grown by 13%.

The overall picture for the pharma industry was positive, but, with the exception of European biopharma, lagged the increase in overall Western equity market prices. The Y&P US Biopharma index increased by 9.1% , the European Biopharma index increased by 15.6%, and the Y&P Generic Pharma decreased by 9.1%.

In terms of trailing price-to-earnings (P/E) ratios at the end of the second half versus year-end 2020, the US biopharma company average was flat at 27.6x versus 27.9x, the Europe average increased dramatically to 35.2x from 27.2x, and the generic pharma company average increased slightly off a low base to 20.5x from 19.2x.

Hence, the pharma stock market performance was positive, but less positive than the overall markets.

PHARMA EQUITY FINANCING AND M&A

Equity issuance dollar volume in the first half of 2021 totaled $9.6 billion versus $27.2 billion for all of 2020. This is a strong dollar showing relative to history, but a slower pace than last year.

The number of offerings, on the other hand, is running at a record pace with 63 offerings completed in the first half, an annualized pace well above the record 85 last year. There were no special-purpose acquisition company (SPAC) IPOs, however.

The most dramatic financial trend development has been the collapse in pharma M&A volume. Only five deals worth $7.2 billion were completed in the first half of 2021 versus 25 deals completed worth $109.1 billion during all of 2020. There was only one of any size—the $3.8 billion acquisition of GW Pharmaceuticals by Jazz Pharmaceuticals.

Clearly, the relative focus has not been on pharma targets, but on biotech acquisitions, partnering, in-licensing, and on internal drug development activities instead of large pharma deals. There is also the recognition that mega deals in the past did deliver cost reduction synergies, but they have been disappointing from a product portfolio and drug development standpoint.

Although there has been a major drop in M&A volume, we expect a pick-up in the near-term based on the current deal backlog. As of June 30, 2021, the dollar value of deals announced but not closed was $44.2 billion (seven deals), the largest of which being AstraZeneca's $43.3 billion purchase of Alexion.

BIOTECH EQUITY MARKET PERFORMANCE

The biotech sector shares have done very well in recent years, fueled by positive news about biotech drug development and the positive perception of the biopharma industry, but performance this year has been volatile. That has been evident in the overall biotech industry stock market showing.

Although the NBI broad biotech index technically increased by 8.8% from Jan. 1 to June 30, one has to look at the fluctuations in between. The NBI climbed from 4,731 at the start of the year to 5,447 on Feb. 8, only to crash thereafter to levels below the start of the year after threatening comments were made about drug pricing by a US senator and mixed comments from FDA about vaccines. What followed was an index that gyrated from 4,600 to 5,100, ending on June 30 at 5,147.

Medium-to-small biotech companies, as a subgroup, did far better, with the Y&P Biotech Mid-Small Cap index increasing by 24.7%, well above the NBI index and the overall market indices.

BIOTECH EQUITY FINANCING AND M&A

The positive story with regard to equity biotech equity offerings continued in the first half of this year. There was a surge in equity offerings, with 228 of them worth $28.1 billion completed in the first half of 2021 versus 375 offerings worth $55.3 billion completed in all of 2020.

In terms of IPOs, there was also a surge—69 IPOs were completed worth $11.2 billion in the first half, compared to 90 IPOs worth $17.5 billion in 2020.

At the current pace, equity issuance will reach record levels. The equity markets fell heavily in love with the biotech sector a few years ago and that love affair has continued, with a slight pause recently.

Biotech M&A activity has been modest historically, with small spurts of activity from time to time. However, that has changed in the last year or so and continued in 2021.

In the first half of this year, activity in terms of the number of deals was on an annualized pace greater than 2020, but not in terms of dollar volume. Seventeen deals worth $11.1 billion were completed versus 32 deals worth $52.8 billion completed in 2020.

The deals are happening at an earlier stage, which is contributing to the smaller average deal size. Not surprisingly, all of the buyers were large pharma companies.

The dollar value of the pipeline of deals as of June 30, 2021 was $5.4 billion (12 deals).

OUTLOOK: PHARMA

Business. The business outlook for pharma manufacturers is positive with regard to drug development and the volume and quality of promising drugs in the pipeline. The industry's innovations in drug development and productivity have improved. Combined with indirect R&D pursuits through the biotech industry, overall development activity has been strong and should continue to be strong.

There has been a shift in emphasis toward orphan drugs, oncology therapies, new innovations such as mRNA, gene therapy, CAR-T, immune system solutions, CRISPR, etc.

The current pandemic has been a plus for the reputation of the industry, but a negative with regard to the ability to execute clinical trials and to maintain industry supply chains.

Generic pharma companies are under severe profit pressures 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.

We think there will be a continued counterbalancing of the positive news versus the business challenges for the biopharma industry.

Equity markets. The stock market prices and valuations of the ethical pharma industry companies have been positive, but not as positive as the overall Western equity markets (with the exception of European ethical pharma organizations). Ethical pharma industry company valuations have been stable due to the netting of positive news coming from the industry during the pandemic with the negative news around pricing and the ongoing R&D and commercial challenges of the industry.

Generic pharma company share prices and valuations, on the other hand, will continue to be suppressed as these companies 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. Since M&A activity has not been as substantial, financing needs continue to be modest.

M&A. Young & Partners expects M&A activity to be modest for the reasons mentioned. Normal strategic fill-ins will continue, with much of the focus on medium-to-large deals with a strategic rationale or a theme around adding new and growing technologies and products. A return to mega deals is highly unlikely.

Separately, pharma companies will continue to be focused on acquiring biotechs, which is affecting the biotech M&A volume. But pharma is also heavily pursuing in-licensing arrangements, partnerships, and joint ventures with biotech organizations and other pharma companies.

OUTLOOK: BIOTECH

Business. The development capabilities of biotech companies have been and should continue to be positive overall, with an escalation in the scale and speed of innovation. The prevalence of orphan-drug opportunities that lower the time to approval, the clinical trial costs, and much smaller sales forces all are favorable for biotech companies.

Although there will be successes and failures by individual organizations, biotech companies have demonstrated their ability to develop new drugs at a faster pace than the larger pharma companies. This trend will continue the rest of this year and well beyond.

Equity markets. Recently, there has been some weakness and volatility in the performance of biotech stocks, but it still has been positive and we expect the market to strongly support biotech companies in the future.

We expect the positive view of the biopharma industry and the regular announcements of successful R&D discoveries and successful clinical trials will continue to fuel the positive stock market treatment of the biotech industry long-term.

Part of the recent volatility this year has been driven by news stories around pricing and the nervousness of the market. We believe price volatility will continue to drive bouts of positive and negative industry news.

Equity financing. Biotech companies will continue to tap the equity markets at high rates for the rest of 2021 and beyond for both IPOs and secondary offerings at record rates as long as the market continues to favor biotechs.

This will be a strong year for biotech company access to funding, as these organizations access the equity markets, and pursue partnering, licensing, and royalty monetization for funding and for shareholder liquidity.

M&A. The number of biotech M&As will continue to be very strong for the rest of 2021 and into 2022, but the absence of large deals will suppress the dollar volume. Many of the deals will continue to be done by big pharma. Buyer interest will be focused on specific targets in favored therapeutic and technology areas and on biotech companies 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 to supplement internal R&D efforts and a large number of biotech company opportunities available. However, M&A valuations will remain challenging, particularly for companies with promising drugs in late-stage clinical trials or awaiting FDA approval, as well as the terms for partnering and in-licensing deals. 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.

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

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

It will be important to have an integrated business and financial/shareholder value strategy. One can easily pursue a development or business strategy that optimizes the odds of a successful product outcome, but it may not create the best financing and shareholder value/liquidity result. From the financial/shareholder value perspective, the key for biotechs will be to properly assess their cash flow requirements and create and execute a flexible financing/M&A plan that properly assesses how much capital is needed and what will create the most shareholder value, whether it is through private placements, partnering, IPOs and secondary offerings, royalty monetizations, or sources of non-dilutive financing. PE