

Biotech Financial and M&A Trends – Two Steps Forward, One Step Back

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Peter Young examines the positive and negative drivers affecting the biotech industry, what happened on the M&A, IPO and financial fronts in 2015, and what to expect in 2016.

2015 was a very exciting year for the biotech industry. Most of the news on the business side for biotech companies was very positive as the industry continued to raise capital, partner with pharma companies and demonstrate a strong ability to develop new drugs in a positive FDA and EMEA approval environment. Similarly, for most of 2015 the biotech industry faced positive trends from a stock market, IPO, venture funding, M&A and partnering perspective.

Unfortunately, some of these trends turned negative in the last third of the year.

Highlighted in this article are these and other details from the “Biotech Strategic, M&A, and Financial Trends Report,” recently completed by Young & Partners (Y&P), that covers all of 2015 and the outlook for the future.

Biotech Business Trends – The Positive Front

The biotech industry has grown significantly and will continue to grow with the positive trends in the use of pharmaceuticals. Biotechnology innovation has been very successful.

Pharmaceutical companies need new products and have bid up prices for acquisitions and licensing deals in certain therapeutic categories and for companies and products that address desirable targets.

The growth of orphan drugs and drugs addressing unmet medical needs in specialty areas has been positive for biotech economics given the shortened development and approval times.

Biologics have become more important and can hold on to their markets longer because production is too complicated and expensive for most generic manufacturers. In addition, the regulatory pathway for biogenerics has been uncertain until recently, especially in the US. The drug industry has received biologics treatment that has been favorable. Innovator biologics

have 12 years of data exclusivity on top of the existing patent lives and biosimilar applications for approval cannot be filed until four years after the first license of the reference innovator biologic.

The stock market has rewarded biotech companies that report positive clinical data and a number of these companies have been able to raise significant capital in follow-on offerings.

Biotech companies have been heavily in favor in the stock market in the last few years until the recent downturn.

The high volume of IPOs since 2013 has provided much needed capital and investor liquidity for the biotech companies at attractive valuations. Venture capital funding has been easily available.

Biotech Business Trends – The Negative Front

There has been a significant drop in the public valuations of biotech companies since the third quarter of 2015 that has accelerated in early 2016. The downturn in the stock market and the negative sentiment about drug pricing has contributed to this drop.

As a result, IPO activity slowed considerably in late 2015 early 2016.

In addition, a number of large biotech companies have faced drug safety, manufacturing, and reimbursement issues and the FDA has been more stringent in demanding proof of safety and efficacy for approval. In addition, the standard has shifted so that drugs must demonstrate that they are more effective than existing drugs in order to be reimbursed.

Biotech Stock Market and Equity Offerings

2015 saw the S&P 500 down 0.7% from the beginning of year. The STOXX Europe 600 increased by 6.8%. The biotech industry saw a run up through July, followed by a significant retreat in August and September and then a recovery. Y&P Large Cap Biotech, Y&P Mid Cap Biotech, and Y&P Small Cap Biotech indices performed well, increasing by 3.0%, 37.0% and 6.4%, respectively for all of 2015. Mid Cap did very well.

However, early 2016 through February was a disaster for the biotech industry as a whole, with a significant decline in share prices. Part of the drop and turmoil has been due to very public concerns over pharmaceutical pricing and the rest has been due to the global market turmoil.

What has been the impact on equity financings and IPOs? Equity issuance in 2015 was quite strong with 206 equity offerings worth \$20 billion completed in 2015 compared to 157 offerings worth \$14.1 billion during all of 2014. IPO activity was strong in 2015, fueled by interest in the sector and the strong performance of biotech stocks for most of the year, but modestly lower

than 2014. In 2015, 61 IPOs were completed that raised a total of \$5.3 billion in new equity compared to 2014 when 72 IPOs were completed totaling \$5.7 billion.

Unfortunately, the general IPO market has collapsed in the first two months of 2016 along with the IPO market for biotechs.

Biotech M&A

Biotech M&A activity has almost always been modest historically, with small spurts of activity from time to time. However, the total dollar value of deals closed in 2015 significantly exceeded the value of deals closed in 2014. In 2015 there were 31 biotech M&A deals completed worth \$18.2 billion. This compares to 28 deals worth \$12.7 billion completed in 2014.

Celgene's acquisition of Receptos was the largest deal at \$7.1 billion.

As of December 30, 2015, the value of deals announced but not closed was very modest at only \$0.1 billion (2 deals).

Why is M&A volume relatively low? Part of the reason is that there have been very active and viable alternatives such as IPOs, secondary equity offerings, partnering and licensing that are being used to provide liquidity and to manage risk.

Is this going to change in 2016? It very well might happen if the current depressed market for biotech stocks and equity financings continues. If the previous flood of inexpensive equity capital continues to be depressed at the current reduced rate, cash hungry biotech companies may be forced to sell themselves if they are faced with a funding crisis.

Biotech: What will the future bring?

The development capabilities of biotech companies have been and will continue to be positive overall. We fully expect that the FDA and EMEA will continue to approve drugs at the current higher rate in the near-term. However, we expect the negative sentiment about biotech and pharma companies from concerns about pricing to persist at least through much of the year.

With the recent collapse in the general and biotech equity issuance and IPO markets, biotech companies will have to turn more to partnering, licensing, debt markets and M&A for funding and shareholder liquidity. It is hard to predict whether the current depressed biotech equity and IPO market will recover to more attractive levels.

The primary biotech M&A theme will continue to be pharma and big biotech acquisitions of biotech companies for pipeline enhancement. The emphasis will be to explore partnering and licensing first and M&A as a secondary alternative, however. Therefore, M&A dollar volume will be solid in 2016, but will continue to be modest compared to M&A volume in pharma.

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