Pharmaceutical
Executive

Pharma and Biotech Financial Forecast: Mostly Sunny

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The last few years have been a positive period overall for both the pharmaceutical and biotechnology industries. Most importantly, there has been a renaissance with regard to the increase in the number of new drugs approved and under development for the two segments of the business.

Many of these innovations are driven by new research methods and the growth of new therapeutic options, such as immune-related oncology drugs, personalized medicine, stem cells, and biologics. We are also witnessing the development of a greater number of drugs that cure diseases rather than just extend life.

The valuations of pharma and biotech companies in the public and M&A markets soared up until August/September of this year in part because of these positive developments. More recently, there has been a setback in public valuations due to the negative publicity about drug pricing.

Pharma's changing landscape

For many years, pharmaceutical companies used their internal research and development capabilities to develop and commercialize drugs in a six-to-10-year timeframe. Given the length of the remaining patent life once the drug was commercialized, the cost of developing that agent, and product pricing in the market place, the economics of drug development and sales were attractive and growth and profitability was high. A multitude of changes occurred that have disrupted that business model.

Pharma companies, large and small, have been forced to shift their strategies and to revamp the way they approach R&D and access to new drugs. Current strategies range from diversification, large-scale mergers, exiting the pharma industry, geographic expansion, regional consolidation, pursuit of biologics, expansion of generics, movement into vaccines, pursuit of orphan and niche drugs, acquiring and partnering with biotech companies, and moving away from primary care indications to specialized areas.

Brent Saunders, the CEO of Allergan, was the keynote speaker on November 3 at the 11th Annual Pharmaceutical Executive Summit hosted by Young & Partners (Y&P), jointly with *Pharm Exec*. In his remarks, Saunders summarized what he sees as the industry's primary challenge: "How do we invest in R&D, which is increasingly expensive as new research tools come on stream; reward our shareholders; and work in partnership with patients and other stakeholders to address unmet medical need? And that's only the starting point."
Saunders noted these pressures were contributing to the restructurings now taking place in pharma and biotech, respectively.

"We in pharma are in the third or fourth inning of a nine-inning consolidation game," Saunders said. "It's real and not going away, because other parts of the healthcare industry are consolidating around us in order to surmount what remains a fragmented, largely inefficient system of delivery and financing. We have to respond to stay competitive."

Generic pharma companies are facing a different set of factors. They have benefited from the patent expirations and the drive by payers to reduce costs. Although the demand for low-cost drugs has been enormous, the decreasing number of blockbuster drugs coming off patent has reduced opportunities for generic producers. All of these developments are forcing generic pharma companies to go into new areas and to consolidate.

Although no clear picture has emerged with regard to who the winners and losers will be, these changes in the environment and the diverse strategies of drug makers are driving the pharma M&A market to a frenzied pace.

The valuations of public pharma companies have soared in the last couple of years, even taking into account the recent setback in prices in August and September.

Looking back, pharma merger and acquisition volume in 2012 and 2013 was fairly soft in terms of the number of deals and the dollar volume.

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> —BRENT SAUNDERS, ALLERGEN CEO

That slower pace was driven by a number of factors. In those years, pharma companies were tentative with regard to attempting larger acquisitions, given a host of uncertainties they were facing. In addition, the valuations of publicly held pharma organizations had gone up considerably, making acquisitions of these companies more expensive.

This changed in 2014 and the first three quarters of 2015, as firms became more aggressive in their pursuit of a variety of strategic changes that require a high level of M&A and related activities.

With regard to financing, on the equity market side, the picture has been positive but modest as pharma companies have not had to go to the equity markets because their earnings, cash flows, and access to debt financing have carried the day. Even IPOs are sparse compared to other industries.

Debt issuance by the pharmaceutical industry has been very strong, driven heavily by acquisition financing and a love affair between the debt markets and pharma.

Boom in biotech

On the biotech side, M&A volume has historically been very modest and that has continued thus far in 2015. This is not entirely surprising since many pharma companies have relied extensively on alternatives such as partnering and licensing. Biotech companies have also had a very strong IPO and secondary equity issuance market that has given them ample funds and an alternative investor exit.

In the stock market, biotech companies have clearly been in favor and the share prices of biotechs have benefited. Investors are excited about the new products and technologies and are strong believers that the biotech business model is working. The recent drop in the stock market and in biotech share values have dented valuations moderately, but most likely on a temporary basis.

In terms of biotech financing, debt issuance continues to be at a virtual standstill, as the debt markets have shunned the biotech sector. However, the situation has been quite the opposite in terms of equity offerings since early 2013. The strong overall IPO market, coupled with the stock market's love affair with biotech, has resulted in a high level of equity issuance, including IPOs.

Pharma stocks: Strong price performance

The first three quarters of 2015 saw the S&P 500 down 6.7% from the beginning of year. The STOXX Europe 600 increased by 1.5%. There was a run-up in prices through July, followed by a meaningful drop that started in August.

The pharma industry outperformed the S&P 500 but is still down from the beginning of the year. There was a run-up through July, followed by a significant retreat in August and September. As a result, through the first three quarters, the Y&P US Pharma index decreased by 5%, the Y&P European Pharma increased by only 3%, and the Y&P Generic index by only 2%.

The valuations of public ethical pharma companies have been damaged but have held up globally. All have been affected by negative stories about drug prices.

From a valuation perspective, the Y&P US Pharma index trailing P/E ratio increased from 25.5× at the end of 2013 to 30.0× at the end of 2014 and retreated to 28.4× at the end of the third quarter of

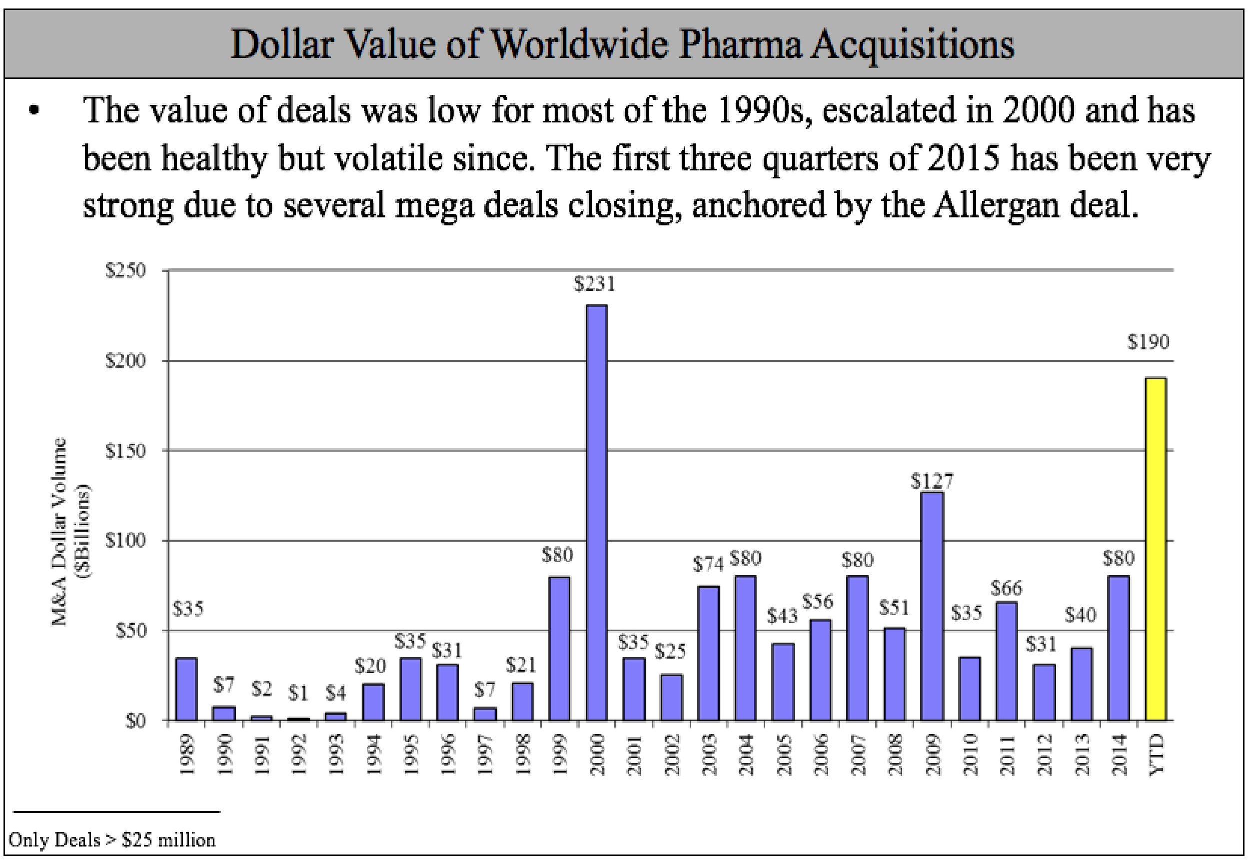
2015. The Y&P European Pharma index increased from 23.6× at the end of 2013 to 28.2× at the end of 2014 and further to 33.0× at the end of the third quarter of 2015.

The Y&P Generic index valuation, after a run-up, fell dramatically. The trailing P/E ratio increased from 27.6× at the end of 2013 to 32.6× at the end of 2014, but fell to 19.9× at the end of the third quarter of 2015, as the market retreated from the sector.

Although these multiples, even with some declines, are a real improvement over just a few years ago, they are still well below where they were 10 years ago when the pharma industry was viewed as a very stable, profitable, high-growth industry and valuations were sky high. The industry has recovered some of its growth and appeal, but it is still less stable and subject to more uncertainties than in the golden years of the late 1990s.

We will see even more positive changes if the industry continues to regain its footing and if and when the market has confidence in the industry's structural stability.

Surge in pharma M&A deal activity



In the first three quarters of 2015, 37 deals were completed worth $190 billion, versus 51 deals completed worth $80.4 billion during all of 2014. This represents a dramatic increase in the dollar activity and an increase in the annualized pace in terms of the numbers of deals. The $68 billion acquisition of Allergan by Actavis contributed significantly to the dollar amount of this year's nine-month total. Activity has been particularly high in the US and Europe.

Drugmakers are acting as both buyers and sellers, forming strategic alliances, swapping assets, shoring up their core businesses, exiting non-core units, and seeking tax inversion advantages.

What does the M&A pipeline look like? There were a large number of deals announced but not closed as of the end of the third quarter. As of September 30, 2015, the value of the deals announced but not closed was $54.7 billion (24 deals), an indication that there is a solid pipeline of deals ahead of us.

Notable announced transactions include Teva's acquisition of Allergan's global generic pharmaceuticals business for $40.5 billion. In addition, there have been a number of large unsolicited offers, such as Mylan's offer for Perrigo (now defunct) and Shire's pending offer for Baxalta.

The recent activity around Pfizer's acquisition of Allergan is an example of a number of drivers of M&A activity coming together: the perceived need to consolidate amongst the pharma companies to combat the growing clout of merg- ing insurance companies, phar- macy benefit managers, and hos-pitals; the ongoing pursuit of the benefits of tax inversions; the desire to build a wider portfolio of therapeutic markets; and the push for marketing, R&D, and other cost synergies. The implication of this deal is a further acceleration of mega consolidation M&As.

Pharma companies have become more aggressive with regard to acquisitions, with companies looking to replenish their pipelines, strengthen their leading businesses, either push their borderline businesses into leadership or an exit, and, in some cases, to re-domicile in more favorable tax jurisdictions via tax inversion transactions.

Pharma debt and equity financing: Limited, but readily available

Pharma companies have generally been perceived as strong cash flow generators, so investors have, thus far, felt comfortable lending to the industry. Borrowing volume has been driven less by investor demand and mostly by the issuers' need for debt financing.

On that note, debt issuance continues to be strong in the pharma industry. In the first three quarters of 2015, non-bank debt issuance was $93 billion, compared to $63.4 billion for all of 2014, a significant increase in activity on an annualized basis. Much of this increase is due to M&A activity.

Equity issuance in the first half of 2015 was also very strong, with $23.7 billion of equity issued, versus $9 billion for all of last year. A significant portion of these equity offerings were com- pleted to fund acquisition transactions and adjust company balance sheets.

There were five pharmaceutical IPOs in the first three quarters of 2015.

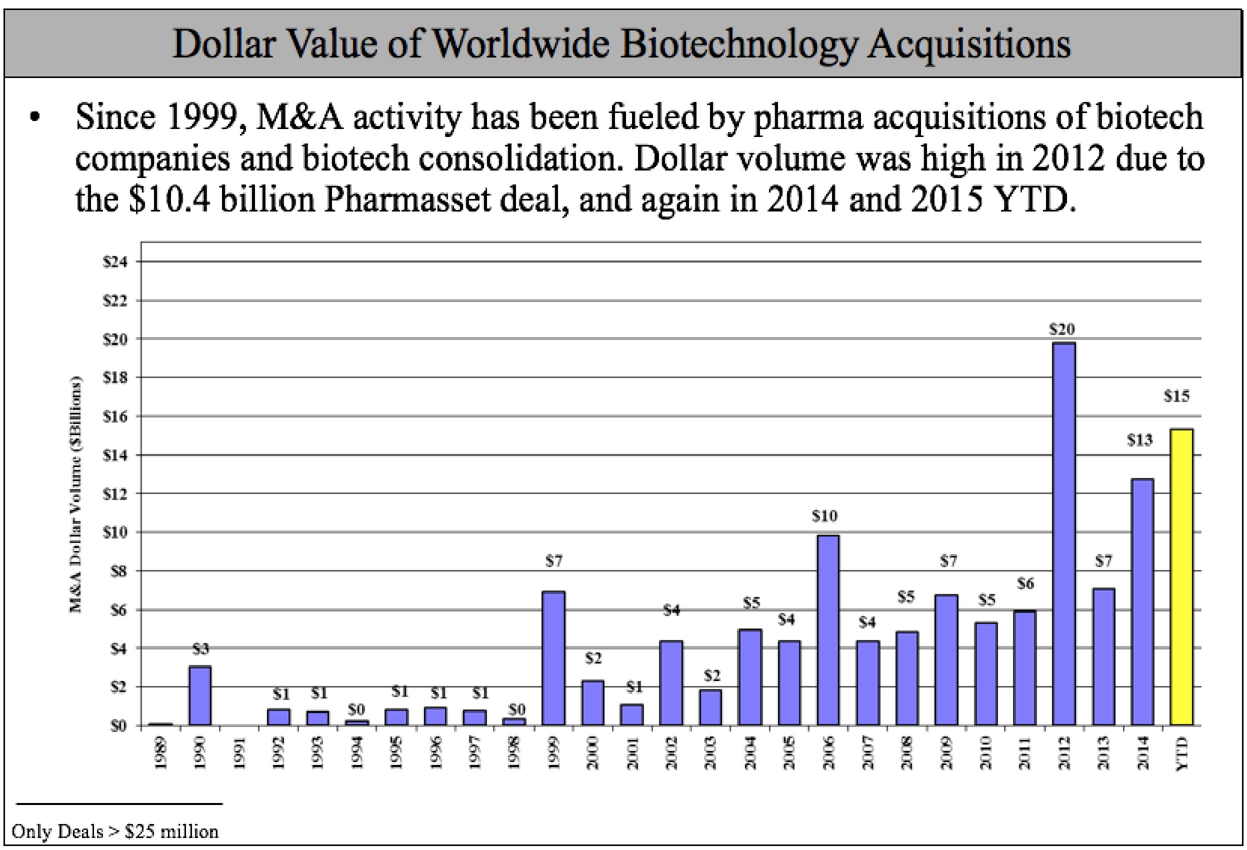
Biotech stock market: A modest setback

For a long time, the market sentiment towards the biotech industry was decidedly mixed, except for established biotech companies and those firms with positive late-stage data. But this sentiment changed in early 2013, and investors fell in love with the industry again. Performance was stellar in 2014 and the first half of 2015.

With the drop in the overall stock market in August/Septem- ber, the Y&P Large Cap Biotech, Y&P Mid Cap Biotech, and Y&P Small Cap Biotech indices decreased by 5.6%, 9.0%, and 6.7% respectively.

The recent decrease in the valuations of public biotech companies have been due to the declines in global equity markets and to concerns about drug pricing that have erupted in the US and elsewhere.

Biotech M&As: Consistently modest



Biotech M&A activity has been modest historically, with spurts of activity from time to time. However, the total dollar value of deals closed in the first three quarters of 2015, although modest, has already exceeded the value of all deals closed in 2014. In the first three quarters of 2015, there were 19 biotech M&A deals completed worth $15.3 billion.

This compares to 27 deals worth $12.7 billion completed in all of 2014.

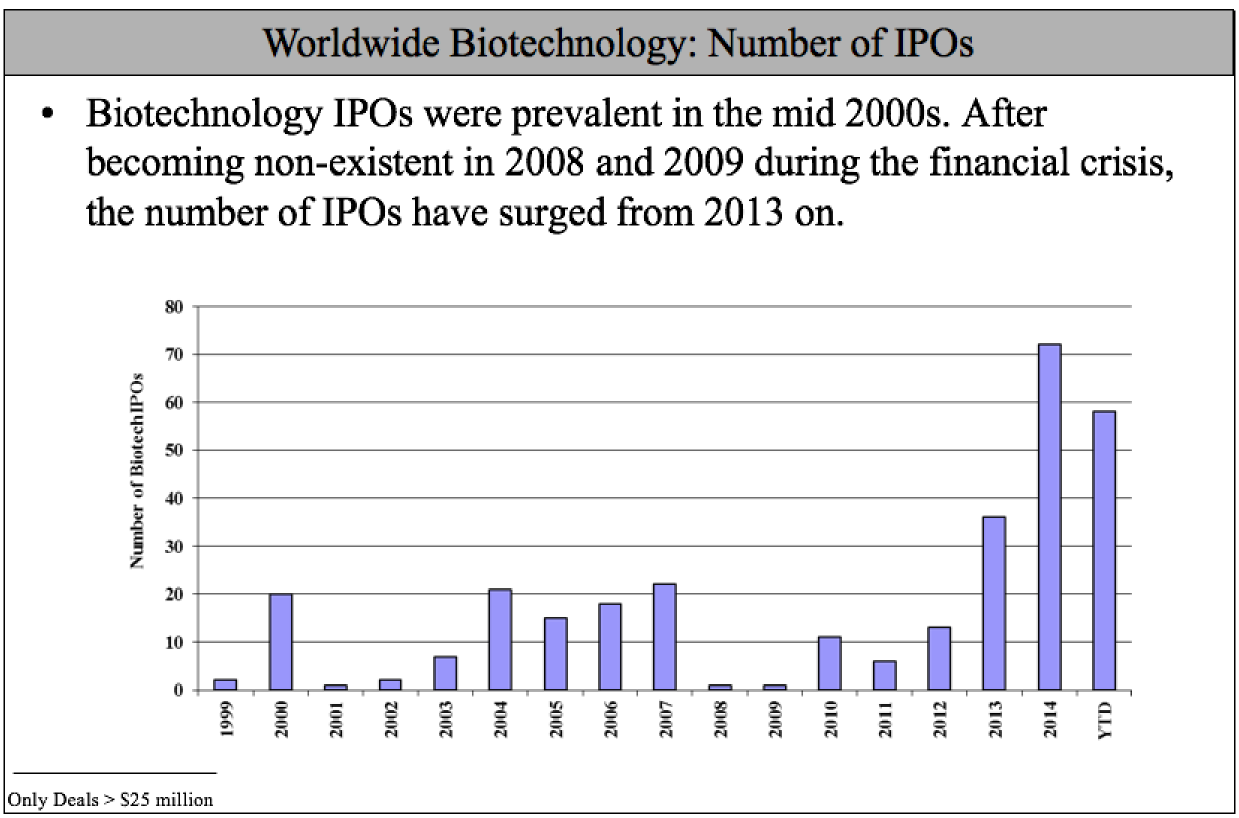
Overall deal activity has been driven by the need of pharma and large biotech companies to expand their pipelines. However, high stock market valuations and the bidding up of prices for late-stage biotech companies have acted as a partial constraint. Also, biotech firms exercised the IPO alternative in 2013, 2014, and the first three quarters of 2015 to achieve both funding and liquidity, as opposed to an outright sale of the company.

In addition, earn-out deals or "structured acquisitions" involving contingent payments continue to be heavily used in biotech M&A deals. The payouts on these arrangements look more like partnering/licensing transactions with milestones for approval or the achievement of specific sales levels which have helped to bridge the gap between buyers and sellers.

As of September 30, 2015, the value of deals announced but not closed was $3.7 billion (seven deals). This suggests a continuation of a solid, but not spectacular, M&A market.

Although pharma and biotech executives believe that there should be a great deal of M&A activity, pharma and biotech companies are accomplishing many of their strategic and financial goals using other alternatives to M&A, such as licensing, partnering, etc. Partnering has been particularly strong. Although the number of licensing deals has fallen somewhat over the last couple of years, the total number of licensing agreements continues to be strong.

Biotech debt and equity financing: Surge in IPOs



Only $224 million of non-bank debt was issued in the first three quarters of 2015, compared to $927 million for all of 2014. In either case, the numbers are small. This supports the historical trend that very little debt is issued by biotech companies.

Equity issuance in the first three quarters of 2015 was quite the opposite, with 205 equity offerings worth $24 billion completed, compared to 167 offerings worth $14.1 billion during all of 2014. Although the environment is not as strong in the fourth quarter, biotech equity offerings are still getting done.

The IPO portion was exceptionally strong in the first three quarters of 2015, fueled by interest in the sector and the strong performance of biotech stocks. In the first three quarters, 58 IPOs were completed that raised $5.8 billion in new equity.

This dollar volume has already exceeded the number for 2014, when 72 IPOs were completed totaling $5.7 billion. It is possible that the number of IPOs will also match or equal 2014 since the industry only needs 14 IPOs in the fourth quarter to match last year's number.

Although there have always been long periods of dormancy between periodic and short biotech IPO peaks, it is not clear how long the current peak period will last.

Pharma: What will the future bring?

The business outlook for pharma companies is mixed, as they struggle to realign themselves to a new business model that will work. The solution will be different for each company. However, there are very positive signs for the health of the industry, as growth has resumed, innovative products have arrived, and certain strategies are bearing fruit.

Big and specialty pharma manufacturers are facing a myriad of business and financial decisions about what strategies to follow and the trade-offs they have to make with regard to dividends and stock repurchases versus acquisitions and internal investments.

Generics have done well in maintaining volume growth, but with high volatility. However, the clear slowdown in patent expirations and the ethical drug company expansions of their generic efforts have forced generic companies to consolidate, acquire, and push into non-generic businesses.

M&A activity will reach near-record levels by the end of 2015. We expect this to continue in 2016, fueled by the massive business restructuring that is happening in pharma and the consolidation that is occurring on both the generic and non-generic sides of the business.

In addition, high stock market valuations have allowed companies to use their shares as an attractive acquisition currency, and there have been selective tax inversion attempts. The recent drop and volatility of pharma share prices will have some dampening effect on M&A, but only in a modest way.

Outside of M&A, the need to fill the shrinking drug pipeline will be facilitated by in-licensing, partnering, and joint ventures—involving pharma and biotech companies, respectively.

Debt financing will end up high this year, driven by the high number and size of M&A transactions that will have to be financed.

Equity issuance will continue to be relatively strong in 2016, as companies rebalance their balance sheets post larger M&A transactions.

Biotech: What will the future bring?

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 are demonstrating their ability to successfully develop new drugs.

Biotech M&A will continue to be active with the primary theme being pharma and big biotech acquisitions of biotech companies for pipeline enhancement. However, M&A dollar volume will continue to be modest, mainly because pharma and big biotech companies are heavily using non-M&A methods to achieve their pipeline goals, such as licensing and partnering.

M&A valuations will continue to be high, with the most promising biotech companies at all stages attracting the greatest interest and relatively high prices.

Historically, the biotech industry's relationship with the debt and equity markets has been volatile. The structural challenge has been the misalignment of when the funding sources or industry acquirers are available versus the time and costs to get to milestones.

However, that has not been the case in the equity market for biotech for the last two years. Venture funding has returned and there has been a dramatic surge in the volume of IPOs since the beginning of 2013. Barring a major disruption in the global equity markets, we expect the positive environment for equity funding to continue. Equity issuance was very strong in the first three quarters of 2015. It remains to be seen, however, whether the biotech IPO window will remain open going forward with the volatility of the equity markets.

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