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BIOTECH: THE BATTLE OVER BIOSIMILARS

Long-term outlook for M&A is more modest

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The life sciences sector has been experiencing a boom in M&A activity, with deal volume in the first half of 2014 running at an unprecedented pace, both in terms of number of deals and aggregate deal volume. With more than $260 billion worth of deals announced in the first half of this year, the industry is up a staggering 220 percent over the same period in 2013, and is already ahead of the full-year deal volume for each of the past eight years. In short — it's a hot market. There are a number of factors driving this deal volume, all of which have come together to create something of a perfect storm for M&A activity. However, while these trends point to a sustained pace of M&A activity over the near-term, a change in the underlying dynamics could bring this boom to an abrupt halt and slow things down to a more middling pace.

Falling Off the Cliff

The effects of the pharmaceutical industry "patent cliff" are well documented and publicized. In 2012 and 2013, large pharmaceutical companies are estimated to have lost a total of $83 billion in revenue due to patent expirations and the subsequent introduction of generic versions of their branded drugs. Although the steepest part of the patent cliff passed in 2012, large pharmaceutical companies are facing expiring patents in 2014 and 2015 covering products generating sales of $34 billion and $66 billion, respectively. In total, an estimated $290 billion of pharmaceutical sales are thought to be at risk due to patent expirations between 2012 and 2018. Such a massive loss of revenue has resulted in some fundamental changes in the pharmaceutical industry.

One of these changes has been the dramatic cutting of R&D expenditures in an effort to maintain profitability. By slashing internal R&D budgets, many of the large pharmaceutical companies have instead opted to outsource drug development, foregoing early-stage drug discovery and development and focusing expenditures on acquiring approved drugs and late-stage assets. It's essentially opting to pursue a "buy-it" approach to business development, rather than a "build-it" approach. However, this change in business model amid declining revenues may not be long-lasting, as the remaining drop-off on the patent cliff is likely not as steep as it first appears.

Many of the drugs coming off patent in 2014 and beyond are biologics, which are biologically derived drugs made from engineered cells or animals (typically delivered via intravenous administration). Because of their complex nature, biologics are subject to a different regulatory approval scheme that did not include a generic option. The Affordable Care Act (also known as "Obamacare") changed that by creating a "pathway" for generic drug companies to introduce copies of biologic drugs (so-called "biosimilars"), although this pathway is just beginning to be utilized and the process for the approval and commercialization of a biosimilar remains subject to some continued uncertainty.

Where there is certainty, however, it's around the fact that the cost and time required to develop a biosimilar will be significantly greater than the cost of developing a traditional generic version of a branded drug. The Federal Trade Commission estimated that developing a biosimilar will take seven to 10 years and $200-250 million in investment; a generic chemical drug costs only $1-5 million and typically takes two to three years to develop. As a result, biosimilars are not expected to be significantly cheaper than the branded equivalent. This means less competition for the branded product and potentially less of a threat to their market share as patent coverage expires. As a result, the effects of the patent cliff over the next several years are likely to be somewhat blunted by the nature of the approved drugs with expiring patent protection.

The effects of the patent cliff in past years, coupled with reduced R&D budgets, have created the fundamental business imperative for many of the recent acquisitions in the life sciences space. However, the willingness of buyers to continue to pay significant premiums for approved or late-stage drug candidates may be somewhat reduced as the patent cliff becomes more manageable, and as improved profitability allows renewed investment in internal R&D programs.

The Rush to the Altar

Another recent trend in M&A that has received significant attention is the increase in offshore "inversions." A corporate inversion is a merger where a U.S. domiciled company merges with a foreign corporation and thereby moves its corporate domicile offshore. As a result of the change in corporate domicile, the newly merged company will no longer be subject to the U.S. territorial tax system, which taxes U.S. corporations on global earnings at U.S. rates, which can be as high as 44 percent in California (combining federal and state tax rates). By taxing foreign earnings at lower rates, the effective global tax burden for the merged company will be lower than it was prior to the inversion.

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The number of corporate inversions has increased dramatically in recent years, with a total of 22 such deals completed since 2011, the majority of which have been consummated in the pharmaceutical industry. The response from politicians and regulators has been swift, with draft legislation proposing to crack down on the moves overseas, including one bill that, if adopted, would apply retroactively to May 2014. While pharmaceutical companies have been largely undeterred, the regulatory response has raised concerns that a window of opportunity for these transactions may be closing soon. As a result, the regulatory backlash may be having the unintended consequence of accelerating near-term interest in these transactions.

Further, the limited number of suitable merger candidates abroad has also created something of a rush to the altar, with U.S.-based companies scrambling in some cases to find suitable foreign merger candidates. While one of the benefits of an inversion is a lower effective tax rate, there is still a need to find a suitable corporate partner, and there are only a limited number of foreign corporations that have the potential to be a good strategic fit with U.S. suitors. A change in the tax rules, whether a targeted change in the inversion regulations or a broader change as part of a reform of the tax code, could significantly slow the pace of tie-ups with foreign targets. Similarly, a dwindling number of suitable foreign merger candidates could also slow inversions, although high U.S. tax rates make almost any foreign jurisdiction potentially more attractive than maintaining one's domicile in the United States.

Market Forces

Finally, overall market dynamics have been a significant contributor to the recent spike in M&A volume. Sustained low interest rates have allowed pharmaceutical companies to borrow money at historically low rates. At the same time, the strong performance of stocks in the life sciences sector has also provided more buoyant equity valuations, allowing pharmaceutical companies to raise capital or issue shares in acquisitions at relatively high prices. Ernst & Young estimated at the beginning of 2014 that large pharmaceutical companies had an additional $100 billion of "firepower" (capacity to conduct M&A deals) based solely on higher stock prices. As a result, buyers have been flush with capital, whether cash or stock for acquisitions, that can be deployed for buyouts.

However, the flip-side of rising market valuations is that target companies are more expensive to acquire. While some buyers have been willing to pay significant premiums in deals this year, that willingness to continue to pay these premiums may diminish as revenue gaps are filled with acquisitions and the near-term imperative for doing deals wanes. Thus, to the extent that biotech valuations remain buoyant (or increase further), it may become increasingly difficult for would-be buyers to justify the premium associated with some of the acquisitions they may otherwise want to pursue.

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While the remainder of 2014 and early 2015 should continue to be robust for M&A activity, a more subdued pace is likely to set in as these macro forces work to rebalance deal dynamics.

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