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Trends in pharmaceutical dealmaking

The number of deals is falling, but they are getting increasingly complex, happening at a later stage, and the number of therapeutic categories is broadening. Cancer remains the most popular category and, across all indications, biologics deals are rising.

by Sarah Terry, Global Managing Director, MedTRACK

The global pharmaceutical market is currently worth about \$820 billion, with growth slowing to a rate of 1.2% over 2008-2014, compared to 10.5% in the prior period (Datamonitor, 2010). This slowdown in growth is largely driven by generic market entry and a drop in the value of key primary care and traditional small-molecule markets. Indeed, Datamonitor estimates that among the top 15 big pharma companies \$70 billion in product revenues is going off patent between 2008 and 2014. And 2011 will be even tougher, with \$31 billion coming off patent, including Pfizer's Lipitor which had \$12.8 billion in sales in 2008.

Importance of biologics

With the value of these markets dropping, companies are looking to expand their portfolios into novel specialty markets comprised of biologics such as therapeutic proteins and monoclonal antibodies. Biologics are a high-value market, with agents costing as much as \$367,000 a year. They are also relatively immune to biosimilar competition. As there are no guidelines for approval in the US and in other markets, approvals have been limited to growth hormones, G-CSF, human insulin, IFN-alpha and EPOs. Currently the European Union is the only market where a concept draft for monoclonal antibodies exists.

The importance of biologics is forecast to increase, with continuous expansion of sales from less than 8% in 2002 to 22% in 2014 for big pharma (Datamonitor, 2010).



This is highlighted by significant mergers and acquisitions (M&A) in the biologics space in recent years: Medimmune (AstraZeneca), Chiron (Novartis), Millenium (Takeda) and Genentech (Roche) to name but a few.

Emerging opportunities

Pharma companies have to enter or expand their positions in generics both at home and abroad by necessity. Datamonitor estimates the current generics market to be at \$270 billion. The emerging generics markets are anticipated to grow by 16% through 2012, compared to 7% for Western Europe and the US (before taking the US Healthcare Reform into account). To miss out on this growth would be corporate suicide, particularly when it comes to emerging markets such

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» as China, where in April 2009 a pledge was made to expand medical insurance and build thousands of hospitals and clinics over a 3-year period as a first step of a 10-year plan to repair the healthcare system.

While M&As targeting prescription drugs still dominate, they have declined from 46% of deals in 2008 to 39% in 2009, while those targeting generics increased from 11% to nearly 20% of all deals. In emerging markets, 42% of deals between 2008 and 2009 were driven by generics, with 58% of all generics-based M&As occurring in emerging markets.

And, while the traditional generics markets are low value, money can still be made. Profitability is driven by the ability to reduce the cost of goods sold, which is done through outsourcing. Pharma is outsourcing more oral solid dosage manufacturing while generics move this capability in-house. The biggest outsourced activities are still product testing and fill/finish, while the least significant is process development and experiment design. The fastest growing is drug discovery and screening, estimated at a worth of \$7 billion (Contract Pharma Jan/Feb 2010).

The outsourcing trend extends into the biologics space, where the convergence between generics and innovators continues. As an example, Daiichi Sankyo acquired Ranbaxy, Sanofi-Aventis and Zentiva. This trend continues with Sanofi Pasteur and Shantha (\$780 million) and Hospira and Orchid (\$400 million). Hospira also acquired a biologics manufacturing facility from Teva's

Pliva subsidiary.

From 2007 to 2008, the number of product-related deals declined from 1,278 to around 1,100. In 2009, the number of deals stabilised at 1,064 (MedTRACK, 2010). And, if the first quarter of 2010 is any indication, it appears that the number of deals in 2010 will look similar.

Reasons for falls in deals

The decline and flattening in dealmaking can be attributed to a variety of mega-trends, including the distraction of merger-related integration and cost cutting. Clearly industry consolidation means there are fewer companies to make deals with.

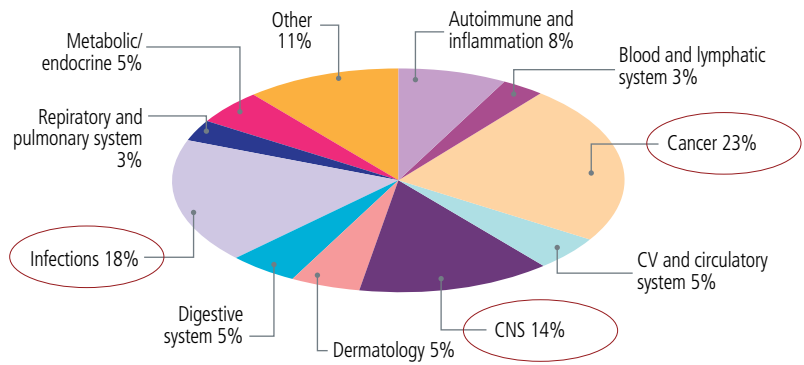
However, even though the number of deals declined, the deals that are being signed are increasingly complex and strategic in nature, covering multiple categories of development with cascading milestone payments and risk-sharing and frequently opt-out clauses. MedTRACK data indicates that nearly a third of deals span multiple categories, whereas only five years ago the number was 10%.

The increased scale of pharma companies exacerbates the effect of declines in product launches and core growth, necessitating continued licensing as a pipeline growth strategy. Thus, it is no surprise that big pharma companies are still the top dealmakers and GlaxoSmithKline (GSK), which did not have the distraction of a big merger, is ranked first with 58 deals in 2009,

Fig 2: Top dealmakers

Company	2009	2008
GlaxoSmithKline plc	58	42
Roche Holding AG	51	48
Bayer AG	45	37
Novartis AG	38	30
Pfizer Inc.	37	43
AstraZeneca plc	35	43
Teva Pharmaceutical Industries Ltd	31	31
Daiichi Sankyo Company, Limited	31	24
Sanofi-Aventis	29	33
Johnson & Johnson	25	38

Fig 3: Product-related deals by therapeutic category



Source: MedTRACK pulled Feb 5 2010

a spot it hasn't held since 2005.

However, AstraZeneca, Sanofi-Aventis, and Johnson & Johnson, who are ranked in the top 10 list of dealmaking, have decreased their activity since 2008, despite not having the distraction of a mega-merger. This will make it even harder for them to compete in the long term. Interestingly, Roche was able to increase its dealmaking activity despite its merger with Genentech, but it still dropped from number one in 2008 to number two in 2009.

Later stage deals

Product deals continue to be focused on specialty markets such as cancer, which are 'high value' segments comprised of therapeutic proteins and monoclonal antibodies, along with high volume markets such as CNS. And while the distribution of deals across therapeutic categories hasn't changed much over the last few years, the stage of development and molecule type is shifting towards more biologics and, subsequently, later stage deals. The number of deals related to biologics increased by 8% from 2008 to 2009. Indeed, more than 50% of products in development are biologic-related.

In the mid-2000s, when competition for late stage products was at a high point, deals were focused on more affordable early stage products, and in 2001 these made up three-quarters of all deals. Fast-forward to 2008 and 2009 and early stage deals comprise only half of all deals. More late-stage dealmaking

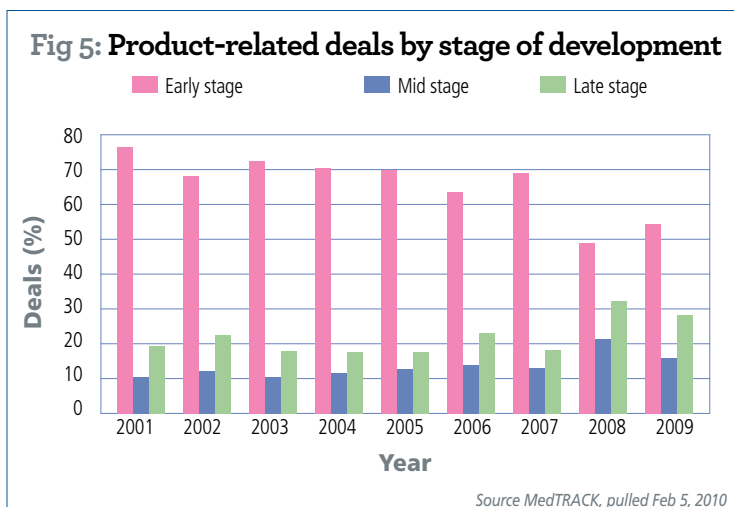
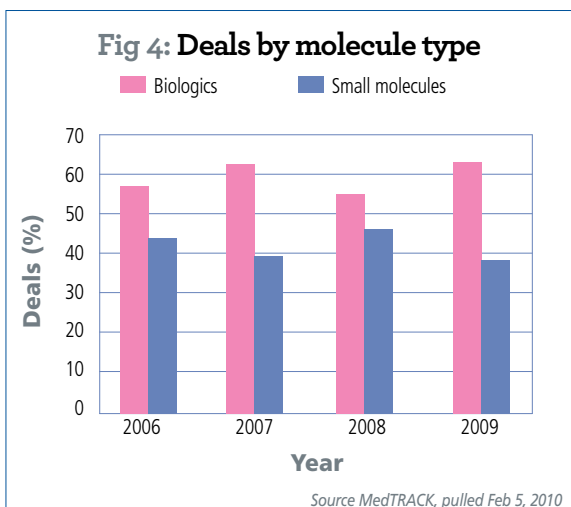
is reflective of a biotech industry running out of cash, as well as of the need to wait longer for biologics in development to achieve proof of concept before they are considered 'deal worthy'.

Furthermore, the cost of biologics-related deals is going up. In 2009 the average initial milestone payment was \$250 million for a biologic and \$152 million for a small molecule: nearly 40% more, as opposed to last year when the difference was only 13% (\$97 million and \$84 million, respectively) (MedTRACK 2010). This may be related to the fact that these are later stage deals but also that biologic-based drugs may have broader applications, across more therapeutic areas, and thus might potentially have higher value.

In the near term we will likely see dealmaking conclude in the highly genericised primary care markets as big pharma finishes establishing itself in generics space and emerging markets. While we expect the number of deals related

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» to biologics to continue to rise, with the impending establishment of a biosimilars approval pathway, companies will need to develop life cycle management strategies for their branded biologics. This includes improving products through easier and less frequent methods of administration, along with companion services to improve compliance and adherence.

Additionally, new biologics-related deals will become even more complex as diagnostics and biomarkers are brought into the fray. Indeed, we expect these deals to occur at earlier stages and have higher values because, with a definable target population, they will gain earlier proof of concept.

Conclusions

The number of deals being made in the last few years is decreasing, even though big pharma are still the top dealmakers. In some cases this is in lieu of mega-mergers (as in the case of GSK) or in spite of them (as in the case of Roche). At the same time, the complexity of deals and the number of therapeutic categories is broadening. Cancer is still the most popular category of interest and, across all indications, more and more deals relate to biologics.

And, while it is important for big pharma to enhance its presence in biologics, it needs to be firmly established in the traditional

small molecule markets both at home and abroad. In developed markets, this is the best way to ensure access to the large aging populations and, in emerging markets, a way to tap into the very large and quickly growing populations. Indeed, efforts are focused at lowering the cost of goods sold by outsourcing, particularly of APIs and fill/finishing in the case of traditional generics, and manufacturing in the case of biologics.

We expect the number of deals in 2010 and 2011 to be relatively flat, but the deals will get more complex and cover more indications as the relevant application of the agents is determined. The products being developed alongside diagnostics and biomarkers will be the most sought after. ■

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