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German life science: turbulent times for biotech companies

In this article, Mariana Brea-Krueger discusses the current situation in the biotech market, and in particular, the situation in Germany. With the slowest sales growth in decades, biotech and pharmaceutical companies are constantly on the lookout for other ways to grow. Mariana offers her thoughts on some of these options, including M&As.

It is a well-known fact that the world pharmaceutical market is faced with the slowest sales growth in decades. In 2011 this growth was 4.8%, based on data from IMS Health. For 2010, this sales growth was a meagre 4.2%. In the 90's, this growth was frequently double digit. We also know that New Chemical Entities' (NCE) success rates have only improved marginally over the standards of 1999. From start to launch, the probability of a product launch was as little as 0.5% and once initial pre-clinical work is started, only 4%. Today, the average cost of bringing an NCE towards launch is between US $500Million and $2Billion and 10 to 11 years of scientific and clinical development is the norm.

Another established fact is the current patent expiry situation facing blockbuster drugs. Approximately $250Billion sales are at risk until 2015 in the pharmaceutical industry, threatened by patent expiries. In 2011 and 2012, these are $22.8Billion of sales at risk due to the expiration of patents for Lipitor™ (Pfizer), Plavix™ (Bristol-Myers Squibb / Sanofi-Aventis), Seroquel™ (AstraZeneca), Singulair™ (Merck) and Actos™ (Takeda). Slowly evolving is the issue of "personalized medicine", which truly does not only mean that for each patient a medicament will be developed, but it most certainly means that certain groups (genetic make-up, stage of disease, etc.) could be treated differently. Nonetheless, this could limit the potential sales of drugs in one or more formulations.

The industry's growth slow-down is among the factors propelling mergers for the purpose of securing NCEs and creating administrative efficiencies. We see this, for example, in Sanofi's acquisition of Genzyme for $20.1Billion which brings Sanofi towards the top of the list of pharmaceutical companies having an excellent pipeline, although streamlining may not have been the goal. The acquisition of biotech companies such as Micromet of Germany being acquired for $1.16Billion by Amgen to secure COR-1 for heart failure is an example of pipeline seeking. There are many different past acquisitions such as Abbott acquiring Solvay for $6.6Billion, etc. We are experiencing employee lay-offs or discussion of lay-offs among prestigious companies such as Roche, Novartis, Sanofi and Merck-Serono, etc. The industry trend is to secure drug pipelines and then consolidate sales forces, administration and R&D in order to thrive in "turbulent" times.

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Research & development (R&D) productivity

As illustrated above, R&D productivity is one of the issues facing the industry. R&D spending has continued to be a record-high, but may not have produced the desired NCEs.

The productivity paradox is still there:

- Pipeline output is low and declining;
- Costs of R&D are rising rapidly, driven by larger and more complex clinical studies and expensive new enabling technologies. Reuters Study (2003a): "On average 1 out of 10,000 substances becomes a marketable product." (Grabowski, Vernon, DiMasi, 2002)

Biotech companies, in the hope of being more successful than pharmaceutical companies, have emerged throughout Europe, the U.S.A. and Asia. These companies believe that they can do R&D better than a large organization, but face difficulties in securing equity capital. Governments throughout Europe have sponsored this segment with millions, if not billions of Euros. The true difficulties lie elsewhere.

The sustainability of these companies is an issue. Biotech companies' life-cycle goal, at least for the European biotech, has been to be acquired or to out-license their technologies. Have biotech companies created sustainable employment in our industry? In the U.S.A.'s early days of biotech emergence, sustainable companies were born. For example, Amgen, Genentech, Chiron, Genzyme, Biogen and Vertex all managed one way or another to survive and continue to develop extraordinary science and create employment. European biotech has unfortunately not done so well.

On the European side, the true emergence of biotech companies happened in the U.K. in the 80's and 90's, whereas in Germany, 1999 was the major "kick-off" year. At this time, the German Government assured investors that they would match 100% of their investment capital. Most importantly, they guaranteed at least 50% of the investor's investment to be returned in the event of insolvency. This produced a "gold-rush" in which venture capitalists (VCs) rushed to Germany to be part of this new "bonanza". At one point in time, business developers were being offered compensation packages worth €7Million in stock options because of the shortage in experienced business developers. Unfortunately, in 1999, the German biotech industry was void of "grey hair" or experienced life science professionals.

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Between 2004 and 2008, the German biotech industry went "belly-up" with an estimated 250 to 450 companies declaring and submitting insolvency or bankruptcy. Triggering this was a unilateral VC panic and desire to secure the 50% government guaranteed amounts. Rumored at the time, was that one of the main private equity groups had written-off €4Billion in losses and had laid-off 20% of its European work force. Partially responsible for this debacle were the German insolvency laws that made it simple to submit insolvency and write-off debt while allowing the option to re-purchase the technology assets for "pennies" without serious consequences. The outcome was a "burned" investment community. Among the press and members of the industry, this debacle was kept very, very quiet. What happened to the far reaching technologies developed by some of these companies? They merged among themselves, they acquired technologies in insolvency and some of the older, pre-boom and more stable biotech companies such as Medigene, Micromet, Mologen and MorphoSys therefore became stronger with better product pipelines. In July 2012, an article in Frankfurter Allgemeine Zeitung cited the current status of the German biotech industry as having €1Billion vested, but with -€400Million in losses.

German biotech companies, as well as the newborn biotech companies, have improved since the "bonanza". They are professional, they have evolved through their "lessons-learned". Currently, the German biotech features 552 companies of which approximately 47.8% are referred to "red" biotech or commercial life sciences. However, although there is plenty of seed capital available due to government sponsoring and Family Offices of high-net worth individuals providing subsidies, there is a serious lack of financing for companies in the clinical study phase. For example, in 2011, VC investments in total biotech were reputed at €146Million. What other sources of cash infusions do biotech companies have other than VCs, pharmaceutical companies' funds and family office funds? Initial public offerings (IPOs), of course, but the world IPO market may never have been worse. We are seeing pharmaceutical and biotech IPOs in 2010 to 2011 in numbers going from 27 to 18, respectfully, and in value from €736Million to €176Million for the same period (IPO Watch Europe 2011, pwc). This is shocking. Forbes published that the US biotech IPO stock performance 2010 to 2011 has been disastrous. For example, the 23 US biotech IPOs of 2010 are down an average of 17% since their initial share price offerings, with 14 of these at 61% below their IPO start price share price level (Life Science Trends 2012, Carlyle & Conlan).

This leaves only one way forward for biotech companies; the pharmaceutical industry. But competing for these buyers are now academia. If we look at world life science transactions, we see that the number of transactions in the first half of 2012 have considerably decreased, too, as well as the value of the transactions between pharmaceutical and biotech. In the first half of 2012, the number of worldwide deals (licenses & joint ventures or JVs) decreased versus the first half of 2011, whereas aggregate total deal size was down -34% (Source: Deloitte Recap LLCs DEAL Builder).

Pharmaceutical to academic transactions are on the rise. Traditionally, pharmaceutical companies were just sponsoring academia, but now these are closing major transactions with them (in-licensing, development services, etc.). For VCs it is a buyer's market, it allows VCs to obtain very low enterprise valuations for, in some cases, very good technologies worth much more. All these developments make it very difficult for biotech companies to thrive. What are they to do? For certain, some biotech companies may survive but the majority may not. For the pharmaceutical industry, this is one option towards securing NCEs that may not be available long-term.

Closing thought:
How can biotech companies secure funding for M&As?

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