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Success rates in biotech – what story do they tell?

The drug development industry is special in many ways. One rarely mentioned particularity is that drug development is relatively well documented. This allows us to quantify drug development risks in terms of success rates. In no other industry we dispose of such detailed risk quantifications: per phase, per indication, per type of compound. As a consequence we rely on these objective quantifications and use them in our valuations; we risk-adjust the cash flows.

But where do these success rates actually come from? Most use success rates published by TUFTS or Kola/Landis. Interestingly, these success rates rely mostly on data from pharmaceutical companies and include few to none biotech company. The common use of these success rates on the other hand is for biotech companies – companies that do not have a product on market, or whose value is significantly governed by not yet approved products. The question arises whether pharma success rates are also applicable to the biotech business model.

We have analysed more than 1,500 projects from public biotech companies over the last 5 years. Already the data gathering revealed some interesting trend: the more projects a company has, the more willing it is to disclose also failures. In most of the cases, a drug just disappears from the pipeline listing without any press release. On the other hand the companies never fail to communicate a positive trial result.

It seems as if smaller biotech companies have trouble in accepting attrition as one of the natural risks in drug development. This observation is in line with the following statement of Richard Pazdur, director of FDA's office of oncologic drugs, in a BusinessWeek interview: "One thing we have seen is a reluctance, sometimes, of smaller companies to make really critical decisions regarding their drugs, whether to curtail the development of a drug. Large companies…. look to abandon that drug to cut their losses. Whereas….. if you only have one drug, then sometimes that is not an option."

Overall we have observed a success rate from IND to market of 20% for public biotech companies. This contrasts dramatically with Kola/Landis' 10% overall success rate for pharmaceutical companies. But more interestingly, the main attrition for pharma happens in phase I and II (87%), while biotech experiences 45% of attrition in phase III or in approval phase. In general the FDA or the EMEA is an objective gate, where a product only passes if it is viable – at least in some way. Nevertheless biotech seems to get relatively more drugs to market than pharma. There are three reasons for this. First, pharma kills the projects earlier and might kill too many of them, but if pharma takes a project to late stage development it has sound economic arguments. A biotech company on the other hand often does not want to give up its supposedly most valuable asset and tries to get it to approval at any costs. Second, the approvals biotech gets might be restricted and need black box labelling. The approvals are often not of the hoped scope. And third, many biotech approvals were not global but just restricted to a few countries. All three

points suggest that overall pharma still achieves much higher returns on investment. First, it pays for less large-scale trials, second, it only takes forward economically promising drugs, and third it then reaches their full global potential. The biotech business model seems to blow up the success rates, but to the detriment of the investors. Joseph DiMasi mentioned 2003 that 30% of all attrition is due to economic reasons; the remaining 70% are for safety, efficacy, or formulation issues. When at least partially negating these economic reasons, then it is only natural that the success rates for biotech are higher.

A more detailed analysis of the success rates broken down by phases and therapeutic area can be found at www.avance.ch/shop/reports.html.