

Success Rates in Public Biotech Companies: NCEs vs. Biologicals

We have performed a study on 211 biotech companies listed on public stock exchanges, tracking their clinical drug candidates for the period of 2003-2009. The aim of the study was to elaborate the difference in success rates for NCEs and for biological drugs - the definition of a biotech company does not lie in the nature of its drugs, but in the maturity of the company. Early stage companies with no, or only a single compound on the market are defined as biotech.

In order to properly evaluate the value of a biotech company, you need to know the probability that the projects make it to the market. As ever more companies embark on the development of biologicals, it is vital to have a good understanding of the involved risk of failure. Historically, the success rates of biological drugs were much higher than chemical compounds. Using those figures for the valuation of biotech companies did not render reasonable results. The question came up whether the published success rates were applicable and representative for smaller biotech companies, i.e. not the Genentechs or Amgens, and whether those companies, much less experienced in drug development are also less successful.

In order to come up with a useful number for the success rates, we have classified a phase as successfully passed when all trials/indications were successful. When only half of the indications passed that phase, then it counts as half success and half failure (a compound where just one, maybe even minor indication made it to the market cannot be counted as a full success, this would be misleading). This means that the success

rates we are looking at are compound specific, not indication specific. In contrast to most other sources for published drug development success rates, we could not rely on the information provided by the companies in their press releases as negative outcomes or drug abandonments often are not disclosed at all. We have complemented the information available through the press releases with reading the annual reports. As many decisions were not stated explicitly, we have assumed that a drug, which is for more than 5 years in the same phase, is not active anymore and counts as failure.

Our results confirm the notion that biologicals have higher success rates from entry into man to approval than NCEs.

Table 1: Compound specific success rates for NCE in biotech companies.

NCE	Failures	Successes	Total	Rate
CP 1	46	236	262	83.8%
CP 2	80	89	169	52.9%
CP 3	34	19	53	35.6%
Approval	7	9	16	56.3%
Overall				8.9%

Table 2: Compound specific success rates for biologicals in biotech companies.

NCE	Failures	Successes	Total	Rate
CP 1	53	236	289	81.6%
CP 2	58	76	134	56.6%
CP 3	19	14	33	42.4%
Approval	2	6	8	75.0%
Overall				14.7%

The overall approval success rates for NCE as well as for biologicals is strikingly low. Only 8.9% of the NCEs and only 14.7% of the biologicals reach the market. The difference is caused by the extremely low probability of success for an NCE to get through clinical phase 3 (35.6%) and approval (56.3%). The consequences of this tendency for NCEs to fail in late stages are devastating. The

company's market capitalisation drops close to zero and the chance of raising new capital to finance the development of the earlier compounds is virtually lost. It is therefore questionable whether small companies should really take the step and push often non-licensable NCEs into late stage development to satisfy shareholders' and analysts' short-term expectations.

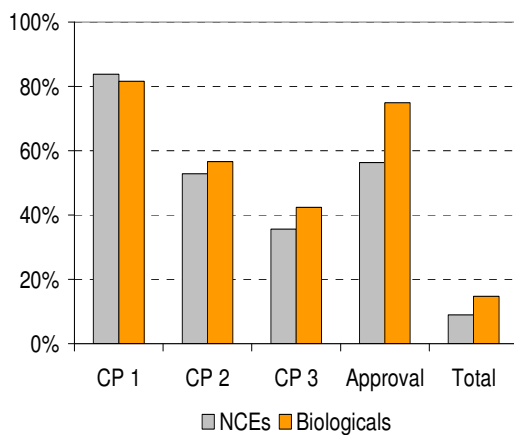


Figure 1: Comparison of success rates for NCEs and biologicals in biotech companies

Only non-licensed compounds were included. This also means that all those compounds that could not be out-licensed are included in the analysis. Only 22% of the NCEs, and only 23% of the biologicals were out-licensed to partners. The success rates for out-licensed compounds are much higher. We will discuss this in a subsequent analysis in more detail.

We summarise that biologicals have a two-fold higher success rate than NCEs in the hands of biotech companies. But for drug classes, the overall success rates remains very low.