



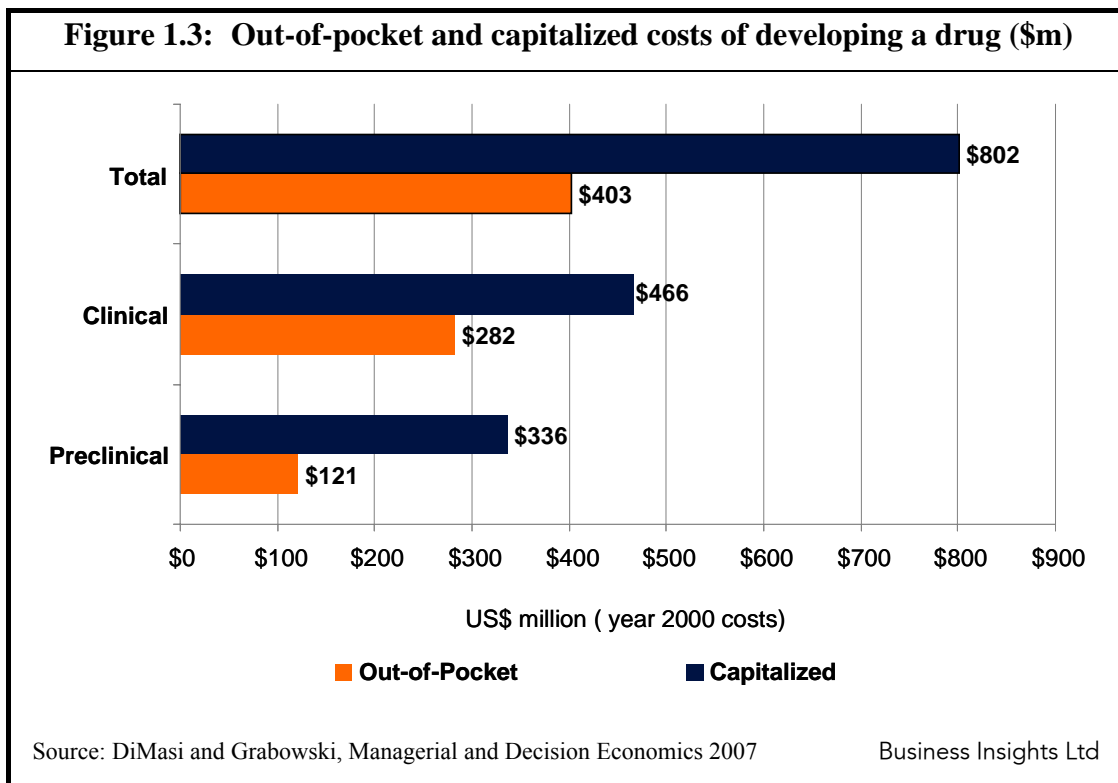
HEALTHCARE

Optimizing Lifecycle Management

Maximizing commercial lifespan through label expansion and combination products

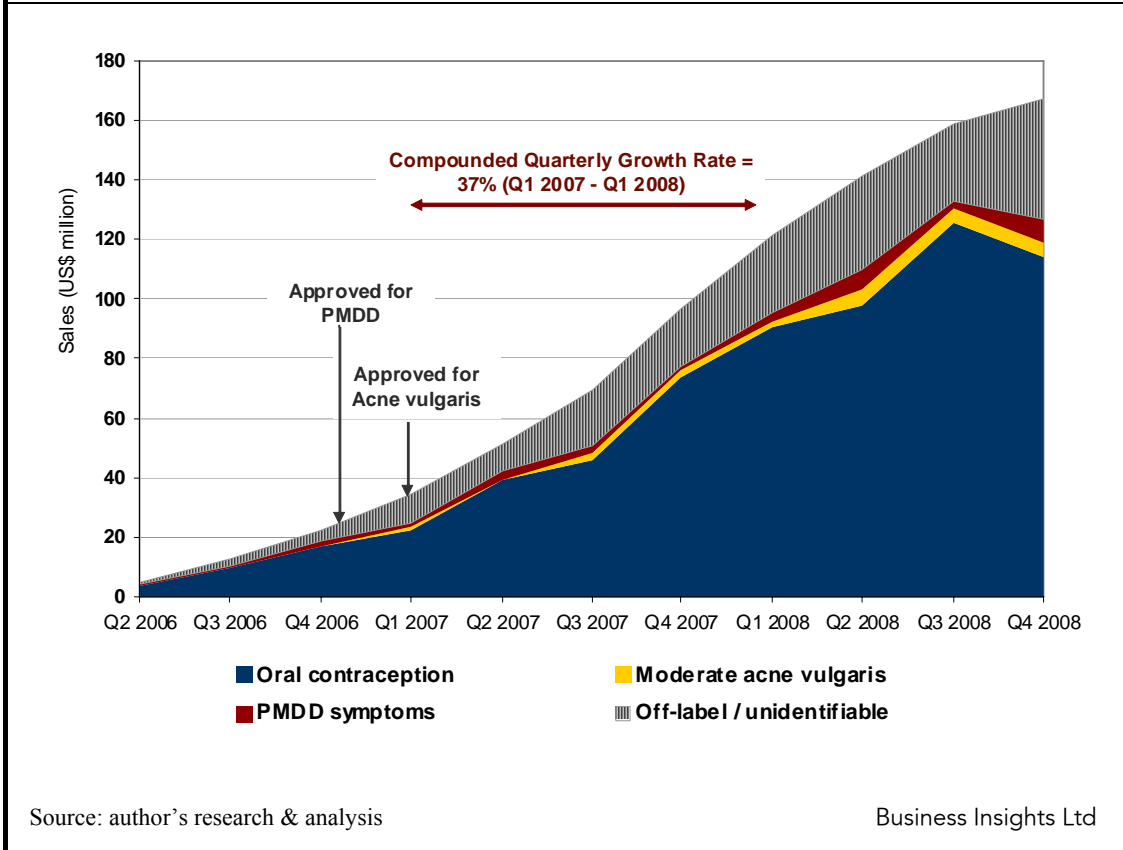
By Gaurav Misra

by Bain & Co judges the success-adjusted investment requirement of developing and launching a pipeline drug to approach US\$2.2 billion in 2008.



Biotechnology-based protein drugs (hereafter referred to as “biologics”) go through longer Phase I and Phase II trials. On average, they require 7 more months of clinical testing before being granted market authorization. However, biologics are subject to much more rigorous post-approval development, as discussed later in this report.

Figure 3.15: Yaz: Label expansion & sales growth - US (\$m), 2006-08



As can be seen from Figure 3.15 above, in the one year period after the two indications were approved, sales revenues by value increased at the rate of 37% per quarter (CQGR). This points to a large increase in drug usage among a wider patient population.

This was despite the fact that the two new indications (PMDD and Acne vulgaris) contributed relatively small amounts to top-line sales. This phenomenon can be partly explained by standard errors in the sampling and primary research process. It is also possible that the two new indications (and the clinical research behind them) provided physicians with greater freedom to prescribe Yaz in a wider patient population beyond the specifics of the approved label.

Chapter 4 Fixed dose combinations

Summary

- ❑ Launching FDCs has emerged as a way to cushion the impact of generic entry, extend the core business lifespan of the parent drug(s) and exploit the full clinical potential of a product asset. FDCs play an important role as a type of follow-on drug or line extension to an established brand.
- ❑ This incremental value added by the FDC over the free combinations can be protected by fresh patents and data exclusivity, thereby extending the number of years the innovator can charge premium prices for the product family.
- ❑ The clinical rationale of the fixed combination needs to be carefully understood and translated into convincing value propositions before committing R&D resources.
- ❑ The most important success factor for an FDC is its ‘synergistic efficacy’. For the brand to be considered superior to the free combination, its specific formulation needs to demonstrate better health outcomes. Payors are reluctant to reimburse premium priced FDCs that only promise compliance advantages because physicians still have the option to prescribe the free combination.
- ❑ Case studies on Vytorin and Advair illustrate the strategies used by managers in maximizing the revenue potential of their product assets via FDC brands. The case study on BiDil shows how a fresh definition of an existing medicine’s market focus created a patentable value proposition that has defined and provided access to large captive market.
- ❑ Some diseases that require multiple therapies are clearly suited towards combination therapy. Examples include diabetes, reversible airway disease, HIV-AIDS therapy, tuberculosis and hypertension.
- ❑ An analysis of drug sales data for hypertension therapy reveals that the Japanese medical community is the least open to FDC usage, followed by the UK and US. Continental Europe is most open to FDC usage among the major markets.