



Anti-Infectives - Market Opportunity or Poison Chalice

With infectious diseases such as HIV, Hepatitis, MRSA and many others making headline news globally on a daily basis, it would be reasonable to think that the business case for investment in R&D for new anti-infectives is clear. Surprisingly however, despite the promise of the considerable rewards offered by a market estimated at \$25bn and rising rapidly, only 1% of the 500 drugs in late-stage clinical development by the world's top 15 pharma companies are antibacterials¹. Equally surprisingly, a recent survey carried out by Essential Science estimated that the global anti-infectives market comprises only around 150 Pharmaceutical and Biotechnology companies directly involved in drug discovery and/or development in the sector. This represents only 5% (by number) of the global drug development community.

Whilst the anti-infectives sector is relatively small it is highly dynamic, reflecting a general trend towards polarisation in the sector. Most of the larger pharmaceutical companies are currently or have recently made strategic decisions on their anti-infectives portfolios. This is giving rise to a general trend within large pharma to deprioritise or indeed withdraw from the sector altogether¹, although anti-virals continue to be an area of significant focus. In the meantime, new biotech franchises are emerging (and merging) regularly with activity in the sector being driven, at least in part, by the licensing opportunities being generated as major pharma rationalise their portfolios.

Whilst major pharma appears to be placing their bets mainly on anti-virals, the Biotech anti-infectives sector seems intent on concentrating on what might be considered "classical" small molecule antibiotics with the majority of companies devoting at least some of their development effort in this area (fig. 1).

Target	Small Molecules including Peptides	Proteins / Antibodies inc. Natural Products	Vaccines
Bacterial Infections	50%	10%	10%
Fungal Infections	10%	5%	<5%
Viral Infections	10%	<5%	5%

Fig. 1, Distribution of Therapeutic Focus by Biotechs in anti-infectives (% companies engaged in anti-infective R&D)

The financial profile of the sector tends to suggest that anti-infectives are a game for the bigger players. Around 50% of companies in the field are already public. The remaining private companies have benefited from an estimated \$1.5bn of private equity injected into the sector over the last 4-5 years. With average deal sizes at Series A of around \$7m and Series B at around \$15m, the sector could be considered expensive from a Venture Capitalist perspective. However, there have been relatively few successful Series A or Series B rounds in the past 2-3 years suggesting that a period of rationalisation is imminent or indeed overdue.

It seems most likely that the anti-infectives sector, and antibiotics in particular, will become the new “orphans” of the pharmaceutical market. Pressure is already being applied to the FDA and other regulators to make development of anti-infectives more commercially viable since, whilst companies continue to pursue compounds that may have the potential for large sales volumes, the majority of compounds that come to the market are likely to be for smaller indications, albeit still generating >\$100m revenues.

Current evidence suggests that the VC community are following the lead of major pharma in tending to withdraw support from this sector despite the fact that there is a strong case to be made for significant returns in the medium term from investment in emerging technology. Given the evolving nature of the sector however, successful exit strategies are likely to be focused more on mid-cap pharma companies including the more mature Biotechs. Whilst major pharma will always compete to access the next anti-infective blockbuster, it is the mid-size companies who are more likely to find the commercial returns of the next generation of anti-infectives most attractive with the opportunity to assemble a portfolio of novel anti-infectives representing a significant revenue generating opportunity.

About This Article

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An experienced life sciences and fine chemical industry executive with an international background in research & development, sales & marketing and business management & consultancy. □ Steve was formerly European Development Manager at Pharmaceutical Advisors, within Solutia's Pharmaceutical Services Division. □ He has been Commercial Director at Prosper Group, Vice President of Sales & Marketing at Sigma-Aldrich Fine Chemicals and spent his early years in R&D at Amersham International.

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ⁱ A Shot in the Arm, Nature, 431, 21/10/04 p892-893