Expert Opinion

9th International drug delivery technologies & deal-making summit

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SRI's 9th International drug delivery summit analysed the current position of drug delivery technologies within the pharmaceutical industry. The classical position of drug delivery as a tool in life cycle management is currently expanding into the primary formulations or even into enabling positions. Using drug delivery as a platform for drug development or redevelopment was recognised as a trend in the industry which is supported by the rapidly growing portion of drug delivery enhanced products already sold as well as by industry initiatives supporting future growth of the sector.

Keywords: deal structures, drug delivery market, net present value

Expert Opin. Drug Deliv. (2005) 2(1):189-190

The SRI meeting was focused on the future position of drug delivery approaches within the industry. The market for drug delivery systems is constantly growing, with a current compound annual growth rate of about 16%, and expected sales in 2005 of $77.8 billion. A component analysis of the total sales of delivery enhanced products revealed a rough 25 – 30% of this total being addressable directly to drug delivery systems and their value creation. This value has increased to a large extent over recent years; for example, from 7% (1995) to 41% (2005) for orally delivered products. The top growing sectors will be oral formulations for cardiovascular and CNS treatments, pulmonary delivery for chronic obstructive pulmonary disease and diabetes, and advanced delivery systems for cancer and adjunct products.

Partnering seems to be typical in an environment with > 300 drug delivery companies offering > 650 technologies. However, three main aspects limit exaggerated expectations: first, many of the technologies lack a sufficient amount of differentiation; second, a good amount of these technologies are merely experimental and lack even preclinical or safety data. Both factors can be potentially overcome by the drug delivery companies themselves or by consolidation. The third factor, however, is that partnerships are only viable for 25% of the total market; 75% of all drug delivery instruments are held inside big pharma. Consequently, overcoming this internal barrier with the much more limited resources of a technology company is the central issue in the partnering game. Often cited developments such as solubilisation technologies become more and more of a commodity. Still, a reported $50 million for the development of a drug delivery technology, multiple opportunities per technology and multi-billion dollar markets keep drug delivery an attractive target for small and midsize enterprises. Given that clearly defined and distinct technologies exist, thorough assessment of the delivery needs for the molecules in question has been made and sufficient data coverage at least at the preclinical level has been established; prospects for partnerings are already good and expected to grow.

Consequently, a distinct focus of the meeting was the financial analysis of license and partnering agreements. No less than three workshops and lectures addressed issues of quantitative value assessment for licensing deals and project evaluation, and provided a rational basis for deal structuring. All models on offer are based on discounted cash flow calculations and generate a net present value (NPV) in a first step. Cost of capital assumptions were made to about 30% for venture capital

money, 10% for equity after going public and about 8% for debt. In a following step, risk is adjusted for the individual stages of a project and scenario NPVs are calculated and weighted. The resulting risk-adjusted NPV (rNPV) at a given state of the project is then used as the central variable of the deal structure. As an industry standard, about 25% of the rNPV can be retained at the licensor, thus determining the deal volume and structure.

Current extensions in the methodology of financial analysis include Monte Carlo Simulations of individual deal as well as the application of such methodology on portfolios. The applicability of real option models was also briefly mentioned.

Workshops were given by QED Technologies, Bioscience Valuation and Charles T Hardy. The latter presenter expanded the methodology towards strategic analysis for shareholders investing in either a high- or a low-risk portfolio at a given stage of development.

In summary, drug delivery systems are expected to grow continuously over the next decade. In contrast to the high-tech-driven developments of the last 5 – 10 years, drug delivery approaches are now moving into the focus, which is particularly well illustrated by Amgen's internal drug delivery initiative. Big pharma seeks to expand patent lifetimes in the battle against biogeneric competitors or actively seeks for line extension and off-label use of existing products. Limited risk and shortened development times in contrast to the development of new chemical entities are the main drivers for these approaches. In turn, drug delivery systems are incorporated earlier into the pharma process, and a growing number of enabling technologies are used in primary developments.

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