Executive Briefing

Rigorous Portfolio Management – A Key to Successful Innovation in the Medical Device Industry

Catenion

The Setting

- The medical device industry has consistently outpaced all other industries including the pharmaceutical industry in the S&P 500 in terms of Total Shareholder Return over the last five years.
- While less affected by the current economic crisis than most other industries, overall growth of the sector is expected to slow down mainly due to increasing cost pressure in healthcare systems across the world.
- Today, the established device markets in developed countries are dominated by a few big players and a multitude of small and regional companies. Competition is intense: New players enter the market with similar products but often at significantly lower cost. The Chinese company Mindray is a good example of a new player pursuing an aggressive cost leadership strategy coupled with an intelligent Marketing & Sales approach. In 2008, Mindray acquired the patient monitoring business of US-based Datascope to get access to established sales channels in the USA and EU. The acquisition created the third-largest player in the global patient monitoring device industry.
- Regional expansion in emerging countries is seen as a significant growth opportunity by many in the medical device industry; however, although growth rates have been promising so far, the overall market size in those countries is still limited: In 2005, markets in the US, EU and Japan represented 85 % of total worldwide expenditures for medical devices, with China accounting for only 2 % of the total. The Chinese market for high-end medical devices remains insignificant to date.

The Role of Innovation

- Cost drives decision-making in the large bottom segment of the global market for medical devices and becomes increasingly important as one of the decision-making criteria in the middle and top end segments as well. However, in our view further growth in the attractive parts of developed markets continues to be driven by innovation and marketing strength against a background of ongoing industry consolidation.
- "Innovation" in this context can be broken down into two categories:

a. Incremental innovation: Successful marketing of medical devices requires continuous updates and improvements to refresh the product lifecycle of established platforms, to keep pace with the competition and to ensure short-term sales.

b. Breakthrough innovation: In addition to the lifecycle management of existing devices, companies need to periodically introduce new platforms and devices that clearly address an unmet need to ensure long-term growth. Better integration across the compartmentalised medical process chains to significantly enhance efficiency and quality of medical decision-making also belongs in this category.

- The organisational requirements of the types of innovation are very different from each other. The predictable pattern of lifecycle management projects requires clear accountability and goal setting, as well as a tight management of timelines and cost. In such a "productivity-led" environment, project teams are best managed based on measurable performance criteria and reward systems. Potential breakthrough projects on the other hand require scientific and engineering excellence and a certain degree of freedom. In such a "creativity-led"

environment, the organisational structure and processes need to be significantly more flexible and less short-term oriented. Such projects are often driven by highly creative and intrinsically motivated engineers and scientists who do not respond well to classical reward systems.

- In addition, the organisational structures and processes need to foster close and continuous interaction of engineers and scientists with practicing physicians, as they are often the source of innovation in the medical device industry. A proactive management of those key opinion leaders from an R&D perspective not only provides fresh ideas for new products, but also helps to drive commercial success by accelerating adoption in the market later on.
- In this briefing document, we focus on some of the difficulties companies are facing in producing a steady stream of innovation of both types and how a novel, more rigorous approach to Portfolio Management can help them achieve this.

Portfolio Management Today

- What then is the situation today? In many companies, R&D pipelines are effectively clogged up by a large number of small lifecycle projects initiated by Marketing and designed to help reach short-term sales targets. Despite the fact that many of these fractional projects have small technical risks and their lifecycles are short, they are often highly interdependent, making portfolio modelling a complex and difficult task.
- In a classic case of “the urgent” dominating “the important”, potential breakthrough innovations with their longer timelines, open-ended functionality and higher levels of technical and marketing risk tend to suffer in terms of staffing and resourcing.
- Worse, with companies attempting to push forward both incremental and breakthrough innovation within the same operating model, many R&D personnel and product managers can dedicate only a fraction of their time to each project they are working on. No wonder companies find themselves in a vicious circle of escalating time pressure, delays and complexity cost from which it becomes difficult to escape.
- Underpinning this picture is the failure of the portfolio management function to effectively support decision-making around priority-setting and resource allocation by senior management.
- In our experience, the portfolio management function in many medical device companies is essentially an administrative function tasked with assembling and formatting information from project teams. It tends to fail in two crucial dimensions:

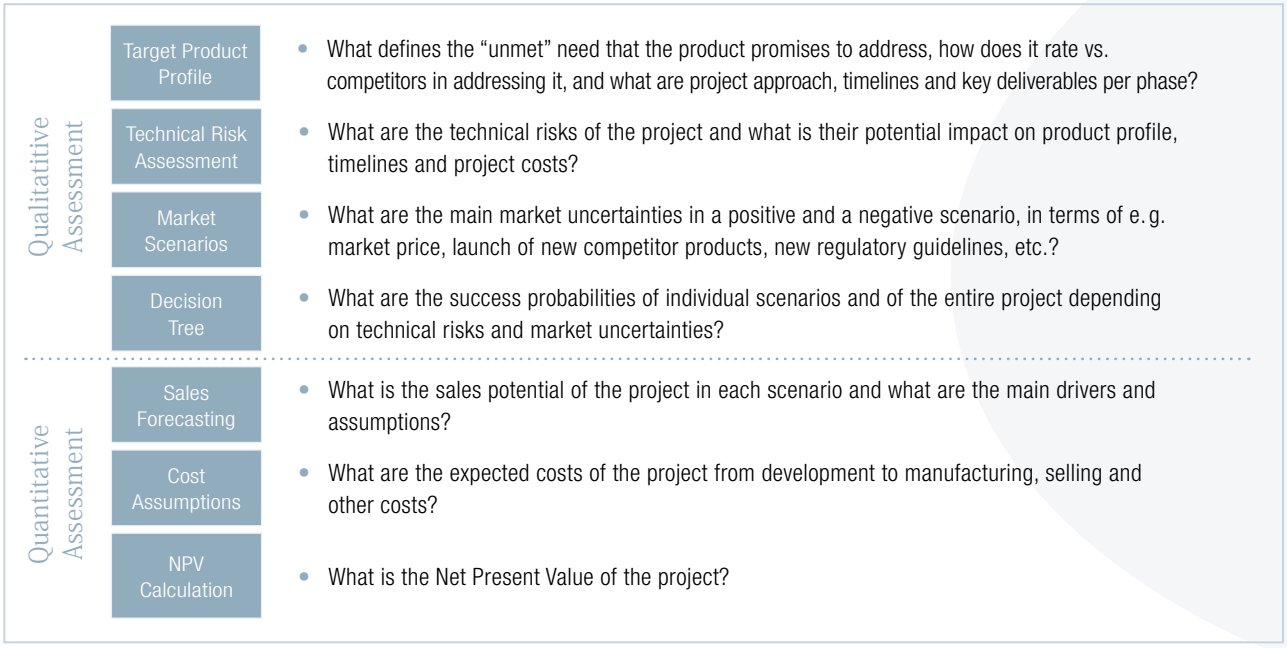
a. Creating transparency: Project teams usually fill in templates describing key characteristics of their project but are insufficiently challenged on their assumptions regarding client benefit, risk, timelines and return potential; serious market research is often lacking and forecasts and NPV calculations are easily manipulated.

b. Supporting prioritisation: Senior Management knows that the numbers are biased and therefore tends to decide on priorities based on who shouts loudest, personal preferences and gut feeling.

- In summary, in these companies R&D management becomes a fire-fighting exercise heavily influenced by the immediate needs of Marketing & Sales with too much focus on short-lived lifecycle extensions at the expense of longer term projects with a potentially much larger value contribution, putting long-term growth and survival at risk.

A More Rigorous Approach to Portfolio Management

- At Catenion we are convinced that medical device companies must adopt a more rigorous approach towards portfolio management in order to escape from the vicious circle of slipping timelines, escalating cost and insufficient resourcing of potential breakthrough innovation.
- Based on our long-standing practice of portfolio management in the pharmaceutical industry and a number of projects for medical device clients, we have developed a methodology for portfolio management that addresses the specific requirements of the medical device industry.
- One could argue that the high complexity of medical device portfolios is partly due to the heterogeneous way in which medicine is practiced globally (various standards of care, different regulations) as well as often confusing patent situations and reimbursement mechanisms. These complexities provide such great a challenge for portfolio management that many companies feel it is not worth the effort.
- Our approach to portfolio management provides project teams, portfolio managers and senior management with a set of tools, methods and processes designed to overcome the weaknesses we have listed above. While soundly rooted in decision analysis theory, we highly value pragmatism and common sense in the evaluation of project potential (reflected in e.g. a differentiated depth of analysis depending on individual project values) and the prioritisation of portfolios.
- Portfolio Management in our view has an analytical and an organisational dimension which are equally important.

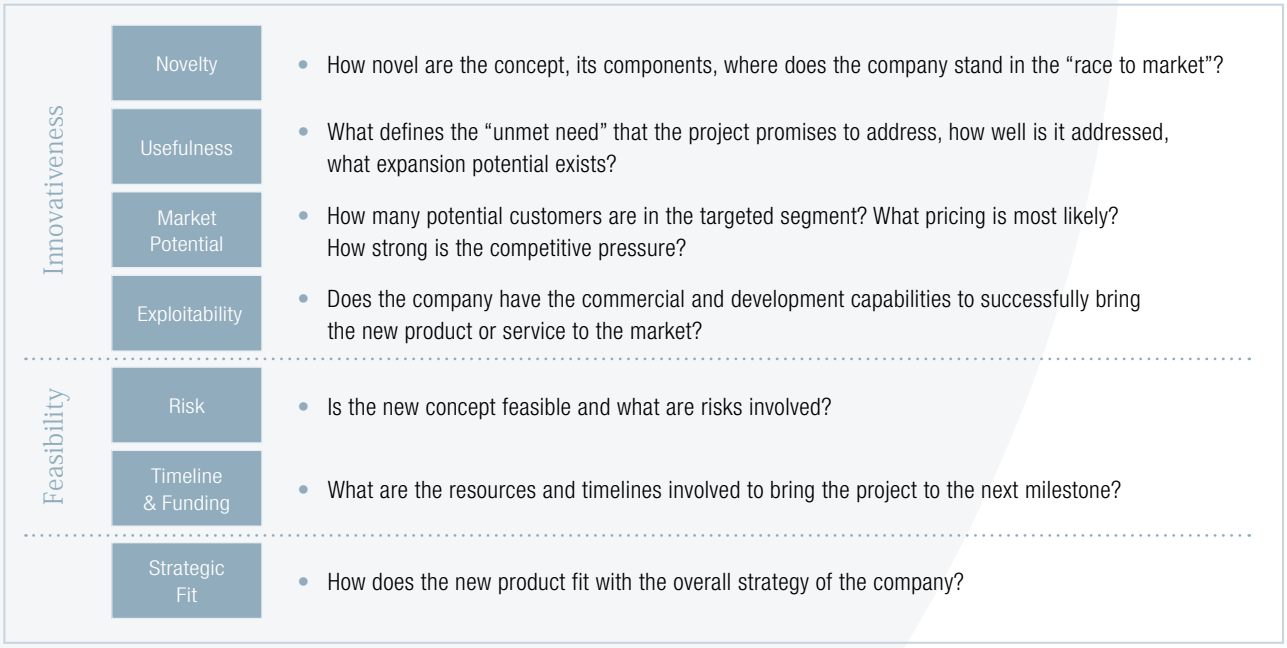


Snapshot 1. Catenion's criteria for review of advanced development projects in the medical device industry

a. To create transparency, projects must be evaluated with a stringent logic that first establishes realistic project claims and then gauges technical and market risk, as well as sales and value potential. We have developed a suite of proprietary tools and methods to help companies do this in a way that takes into account the different types and stages of innovation which characterise the industry.

b. In organisational terms, we advocate a strong and independent portfolio management function. Being strong implies having both the authority and the capability to challenge project teams in-depth regarding proposed project strategies and the underlying assumptions. Independence is a pre-requisite for being able to submit analytically-driven proposals for prioritisation and resource allocation to decision-making bodies and challenging senior management to base their decisions on facts as opposed to preferences and expediency.

- Experience shows that when strength and independence are given, Portfolio Management can provide crucial support for management to effectively deal with the complexities of timelines, escalating cost and conflicting priorities discussed above. In addition, it can provide an essential input into a company's process of strategy development by providing a clear bottom-up picture on the strengths and capabilities of the organisation as compared to the competition.



Snapshot 2. Catenion's criteria for assessment of early-stage research projects in the medical device industry

Outlook

- To establish such a Portfolio Management function is a big step ahead for many companies. Once this is done, a differentiation in the operating model to more effectively deal with the conflicting requirements of incremental and breakthrough innovation should be undertaken. Some of our clients have found the clear separation of budgets to be an important first step in this direction.
- In summary, then, it is the objective of our approach to portfolio management in medical device companies to help clients reach their full innovation potential. We do this by establishing the tools, methods, processes and the organisation that can create a balanced portfolio of incremental and breakthrough innovations addressing both the short-term needs of the Sales organisation and the long-term requirements of sustained growth.
- As part of our consulting philosophy, we support implementation through on-the-job-training for portfolio managers and project teams in our decision analysis-based methodology so that the process will run smoothly without external support after the initial round. Additional training is delivered by our sister company The Catenion Academy and uses case studies to provide real life experience to participants.

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Catenion: Your Partners for Pharmaceutical Strategy and Innovation

Catenion is a management consulting firm devoted to helping pharmaceutical and medical products companies significantly increase the returns on their R&D and Marketing investments by creating more innovative and effective strategies and organizations.

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