Analytical Marketing

Better decision making for evaluating new medical device projects: A real options approach

Received (in revised form): 26th July, 2007

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Keywords real options, strategy management, product evaluation, medical devices, financial modelling, new product development

Abstract This paper addresses some of the issues facing new product development in the medical device sector and reviews some of the financial decision-making methods currently used to aid in project selection. The fundamental limitations and deficiencies of these methods are discussed. An alternative, real options (RO)-based approach to project management is proposed as a much better way of managing uncertainties and understanding the relationships between the risk and the opportunities in a product development lifecycle. Although the RO technique is not especially new, its application to the medical device sector is novel. An RO valuation example, using a binomial lattice approach, is given and the implications for project selection and company strategy are discussed.


INTRODUCTION

The need for new product development

New products are crucial for the growth and prosperity of any company.

Companies must innovate to respond to technological advances, meet regulatory requirements, cope with competitive threats and keep pace with market and consumer needs. In a survey of 150 European medical device companies, 63 per cent said that they had produced/offered an innovative product or service in the last 12 months and 82 per cent were planning to launch a new product within
the next two years.\textsuperscript{2} New technology and new project development projects are, however, associated with risk and uncertainty. Managers are faced with the dilemma of whether or not to invest at any stage in the new product development (NPD) process, with the concept screening stage perhaps being the most critical point for investment.\textsuperscript{3} As this uncertainty is unavoidable, the successful identification, analysis and management of uncertainty and risk are necessary steps in enhancing the likelihood of new project success.

The problems in medical device development are inherently complex, with manufacturers faced with having to navigate regulatory pathways, prove cost and clinical effectiveness, and traverse through the various reimbursement and regulatory environments of different markets, the available evidence to support the decision-making process at an early stage is incomplete and highly uncertain. The challenge is to develop more robust methods for dealing with these uncertainties, especially those at the earliest stage of development where there is the largest information deficit resulting in the highest uncertainty.

The real options (RO) technique has been upheld as a superior technique to traditional methods of valuation such as net present value (NPV) and payback period, for characterising strategic and financial value to account for future risk and the ability of management to be flexible in their decision making. This paper applies this technique to a hypothetical situation in which a medical device company is contemplating financial investment in the development of a new product to demonstrate how RO analysis can be used in the decision to finance the development of a medical device, and examines some of the issues facing medical device companies who wish to use this technique.

**NPD in the medical device sector**

The innovation process in commissioning a new medical device is usually captured by formal product development processes, such as stage gate systems,\textsuperscript{4,5} to maximise resources and increase efficiency. The process begins with a ‘concept’ or ‘idea’ and ends with a successful launch. A simplified four-stage generic process for medical device development is summarised in Figure 1.\textsuperscript{6}

The stages are separated by decision points or ‘gates’, each of these representing a go/abandon/re-assess decision. At each decision point, new information that has become available since the previous decision point can be taken into account and in this way management flexibility

![Figure 1: Product development stages](Image)
can be included. This paper is concerned with assessing the financial value of keeping an opportunity ‘alive’ at these decision points.

EXISTING TECHNIQUES AND PRACTICE

The decision-making process in medical device NPD can take into account many factors including user needs, regulatory and reimbursement requirements, resource allocation feasibility, technological innovation and opportunities, competitor analysis and the overall company strategic requirements. The success of any product will, however, usually be measured by its revenue stream and number of sales, and hence a prediction of the project net worth will usually drive the initial business plan and influence NPD strategy.

In a consultation exercise with the medical device sector in the UK, 7 senior managers of a number of medical device companies were asked about their current capital budgeting and project valuation techniques. Most companies said that they perform formal economic evaluation on development proposals when determining the acceptability of new projects, which is carried out either at the concept stage or after a phase of basic research. A combination of payback analysis and discounted cash flow (DCF) techniques such as NPV were most frequently used. These findings are in consonance with results of capital budgeting surveys from other industrial sectors.8–10

The payback method and DCF analysis are relatively easy to use and understand and provide clear, consistent decision criteria for projects. They are firmly embedded in the mindset of financial departments. Some fundamental limitations of these techniques were, however, cited by respondents, which could lead to under-valuing investment opportunities and rejecting projects with negative NPV prematurely. DCF assumes that there is a single line of development for a project that is carried on to completion regardless of changing events and circumstances in a project lifecycle. It assumes that management is passive and does not recognise the reality of management intervention and flexibility. The RO technique attempts to overcome these deficiencies.

RO-BASED ANALYSIS

The RO method applies financial theory to value investment opportunities in real markets — the markets for products and services. RO grew out of the methods used to value financial option contracts and in response to the dissatisfaction with traditional techniques of capital budgeting based on DCF (NPV) techniques.11 It seeks to counter the deficiencies of these techniques by recognising that managers have the flexibility to adapt and revise capital budgeting decisions in the future as new information arrives and future uncertainties are resolved. Indeed, this flexibility and uncertainty can add significant value to a project.

An option provides the holder with the right, but not the obligation, to buy (call option) or sell (put option) a specified asset at a pre-specified price (known as the exercise price or strike price) on or before a pre-selected date (known as the expiration or maturity date). NPD is essentially made up of a sequence of investment stages analogous to options; there is an opportunity, but not an obligation, to go ahead with each stage. For example, an RO occurs in a research and development (R&D) process that enables a company to launch a new product giving the stakeholders the ‘right, but not the obligation’ to do so. Even if the R&D phase is successful, the market may not yet be favourable for the launch of the new product. NPV schemes ignore such options.
Faulkner provides an excellent survey on the use of options thinking in R&D project valuation. Merck used option analysis to evaluate a proposed business relationship with a small biotechnology company code-named gamma in order to gain access to their new technologies at early stages of development. Lint and Pennings considered the NPD process at Phillips Electronics and use an RO to give explicit decision rules in order to derive economic criteria for the go/no-go decision before and after the R&D stage, including the decision to launch a new product on to the market. Neely and Neufville develop a hybrid RO approach that combines decision analysis and options analysis into a practical means of accurate valuation of projects and apply this to the R&D programme of a major automotive manufacturer. Rogers et al. develop a stochastic programming-based model of pharmaceutical R&D portfolio management using an RO decision tree approach for making optimal project selection decisions and to value the uncertainty of candidate drugs. Kellogg and Charnes compute the value of a biotechnology firm as the sum of the values of its current projects. Cameron and Bashshur have suggested an RO model for the financial evaluation of telemedicine.

ASSESSING THE VALUE OF A MEDICAL DEVICE: AN EXAMPLE

Setting the scene
Companies are often confronted with new product ideas that may seem promising but will invariably be risky and costly to develop. The usual practice is to build a business model to estimate future profitability, by incorporating costs of development, marketing etc and the likely revenue stream. Although based on limited data, these models can have a large influence on the decision to continue or terminate a project's development. At the very least they help inform the strategy of development in terms of optimising profit. Many companies, particularly the larger ones, will reject projects with a very long payback period or negative NPV. For start-up medical device companies, business models also help them to engage with investors in their quest to raise funding. As stated above, it is evident that many medical device companies, in common with many other industries, use the standard payback period or NPV techniques for business valuation. While these techniques provide a good benchmark for valuation, there is a concern that many 'good' projects may be rejected at an early stage particularly those who appear on the borderline between being rejected or accepted. The following example, while hypothetical, demonstrates these issues.

Example
As an example, consider a proposed R&D project to develop a noninvasive blood glucose monitoring device. The market for 'similar' devices is in its infancy but is predicted to grow rapidly and hence future financial returns are highly uncertain. The company wishes to develop their own device to enter the market but also hopes to introduce enough technical innovation into the device to establish and maintain clear product differentiation with competitors. The R&D outcome is as yet uncertain and some technical barriers are still to be overcome. Despite the uncertainty, the company is keen on getting a foothold in the market as potential returns could be high. Should the company invest in the technology? Although this is a simple example it is typical of many real new project evaluation scenarios.

The project development process is assumed to follow the stage gate process as shown in Figure 1, with opportunities to
invest at each gate. The first stage is to verify that the concept is technically feasible, carry out a patent search and literature survey and do a very basic design review. This is done at a cost of $50,000 at \( t=0 \) years. If the proposal looks promising the company will commit to spending $175,000 at \( t=1 \) years. The project will then be assigned a project team, conceptual designs modelled and built, user trials conducted, a detailed market survey carried out and the design finalised. Should this preliminary investigation prove successful, then the company will proceed with the project and invest in manufacturing equipment, order parts, develop a prototype together with samples for customers and seek regulatory approval. This will be in year 2 of the project at a cost of $500,000. Should the prototype prove technically successful, be welcomed by customer representatives and user groups, then the next stage is to invest in full-scale manufacture and in the launch of the device into the marketplace. The investment required for this phase will be $1.5m. These costs and timescales are summarised in Table 1 together with the stage-related probabilities of success, which are estimated from past experiences of product development processes within the company.

A market/competitor analysis and brainstorm session of technical and marketing executives within the company estimates that, assuming that stage 4 is successful (90 per cent probability), the possible financial returns are estimated to be 'high', 'medium' or 'low' with probabilities of 0.2, 0.6 and 0.2, respectively. For simplicity, the financial returns shown are the returns over the life of the product brought back to the date of the launch as an NPV. A decision tree (Figure 2) represents the investment decision points (DP), stage costs outcomes and the present value (PV) of future cash flows (FCF). The stage-related probabilities of success are also outlined.

‘Traditional’ expected net present value (ENPV) calculation. Figure 3 describes the calculation of ENPV, a ‘traditional’ method of calculating value, which is based on the discounting of the free cash flows generated by the project at the company’s weighted average cost of capital (12 per cent). The ENPV for this glucose monitor project is calculated as $-53,041 and hence the continuation of the blood glucose monitoring project may be doubtful considering its negative NPV.

The ENPV analysis assumes that the project is left to chance. It disregards the added value that can be brought to the project by a manager’s flexibility to intervene at any stage of the development process and change its course in reaction to a change in economic or market conditions. Instead, the ENPV analysis assumes that once a stage is completed and if it is successful the company will automatically invest in the subsequent phase. In practice, the successful completion of a particular development stage may be accompanied by other factors that will affect the profitability of the product. For example, if a competitor

<table>
<thead>
<tr>
<th>Stage</th>
<th>Cost (£)</th>
<th>Timing of investment</th>
<th>Years in stage</th>
<th>Probability of success (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>50,000</td>
<td>( t=0 )</td>
<td>1</td>
<td>40</td>
</tr>
<tr>
<td>2</td>
<td>175,000</td>
<td>( t=1 )</td>
<td>1</td>
<td>50</td>
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<tr>
<td>3</td>
<td>500,000</td>
<td>( t=2 )</td>
<td>2</td>
<td>50</td>
</tr>
<tr>
<td>4</td>
<td>1,500,000</td>
<td>( t=4 )</td>
<td>0</td>
<td>90</td>
</tr>
</tbody>
</table>
launches a similar product first, it may be better for a company to stop the project even if it is technically successful and even if it means losing the investment up to that point.

The other weakness of this type of analysis is that it uses a constant discount rate throughout the development phase. This assumes that the level of risk at each decision point is constant. In practice, different stages of development will have different levels of systematic risk and should be discounted at different rates. Project risk invariably changes due to changes in the environment and management intervention. The RO technique attempts to overcome these problems.

**RO approach.** In the RO approach, each sequential investment is considered a call option involving a future decision to invest in further development when the outcome is successful. At any point in the
development, the project can be abandoned so that only the sunk cost is lost.

There are a number of ways of valuing options, but to demonstrate the principal a replicating portfolio method is used here to determine the market valuation and discount rates for the project. This approach uses a simple binomial model to analyse the investment options in the product development of the project. The model is based on a risk-neutral probability options valuation approach using a ‘risk-free’ interest rate. In this approach a risk-free ‘twin security’ or ‘replicating hedge portfolio’ is now set up, which has exactly the same upside and downside values as the RO in each period. The return of this security has to be perfectly correlated with the payoff from the RO. In lieu of an external twin security that exactly matches the payouts of the project, real-options practitioners often use the PV of the project itself, without flexibility, as the underlying risky asset of managerial flexibility. The risk in the option is correlated exactly with the risk of its underlying (the project in this case). A portfolio of option and a finely judged amount of project is created. The amount is selected so that the risk is entirely eliminated and so the project is discounted at the risk-free rate.

The current value of the project is found by discounting the value of the expected commercialisation cash flows to time zero:

\[
EV = (0.2 \times 1,000) + (0.6 \times 2,500) + (0.2 \times 12,000) = £4,100.
\]

Volatility is the unpredictability of FCF related to the asset. More precisely, it is the standard deviation of the growth rate of the value of future cash inflows associated with it and essentially it is a measure of economic uncertainty. Estimating a volatility value for RO is certainly nontrivial and in many cases is a weakness in an RO valuation. This is discussed further in the conclusions.

In this example, volatility is based on projections of the project’s FCF using the DCF valuation and variance in cash flows, \( \nu = (0.2 \times 1,000^2 + 0.6 \times 2,500^2 + 0.2 \times 12,000^2) - 4,100^2 = 1.594 \times 10^7 \). The annual standard deviation of the underlying cash flow is given by the square root law of time, see equation (1):

\[
\sigma = \frac{\sqrt{\nu}}{EV \sqrt{T}} = 0.4869
\]

where \( T \) is the time to acquire the FCF (\( T = 4 \)). The PV of the FCF is given by \( EPV = 4,100,000 / (1 + 0.12)^4 = £2,605,624 \).

The binomial model relies on calculating ‘up’ (\( u \)) and ‘down’ (\( d \)) multipliers and the risk-neutral probability \( p \), see Appendix A. These are calculated as \( u = 1.627 \) and \( d = 0.615 \) and \( p = 0.423 \). The risk-free rate used here is 4.34 per cent, which is the November 2005 UK monthly average short (five-year) gilt yield.

Using the up and down multipliers, a binomial lattice of asset values is constructed with the initial value of the lattice given by the calculated EPV. The following values until launch of the product are calculated using the up and down multipliers (and depend on whether economic uncertainty resolves in a favourable or unfavourable manner). Table 2 illustrates the movements in gross EPV depending on economic conditions. Technological and economic uncertainties are treated separately. The economic uncertainty is included in Table 2. The technological uncertainty is represented by the probability of success (see Table 1).

RO enable managers not to commit to all stages of funding immediately. Instead, the product development lifecycle is analogous to a call option, in the sense that the subsequent stages of development are only worth investing in if future projected cash flows exceed the investment cost of the previous stage. In other words, the company earns the right but not the
obligation to invest in the future commercial project. As with decision tree analyses, the calculation of the option value is started at the end of the tree (last column of Table 3) with computation of the payoffs. The payoffs are given by

\[ c = \text{MAX}(\text{cashflow} - \text{investment}, 0) \]  

(2)

If the payoff is negative (economic/market conditions are unfavourable), then the company can abandon the project without funding stage 4 and only losing the initial stage 1–3 costs. This is incorporated in the calculation by defining the value of the payoff as the highest of NPV of stage 4 (commercialisation) or 0 (abandoning the project), as in equation (2).

The option values are shown in Table 3. This calculation is repeated for the five values that make up the last column of the option value tree. These option values are now rolled back in time using risk-neutral probabilities and the success probabilities and staged investment costs are incorporated (equation (3)) to calculate option values for each node.

Option value at time \( t \)

\[ V_t = \text{MAX} \left[ \frac{(pV_{t+1}^{\text{Up}} + (1-p)V_{t+1}^{\text{Down}})}{1+r_f} - I_t, 0 \right] \]  

(3)

where \( V_t \) is the real option price at time \( t \), \( p_{T(i)} \) the probability of technical success at stage I and \( I_t \) the investment cost at stage \( i \). (When the stage of development has a duration of more than one year, \( p_{T(i)} \) is the probability of success for that stage in the final year of that stage and 1 for all other years.)

This process is repeated to the first node, thus obtaining the value of the option of £4,716. The figure represents the PV of the project including the value of abandoning the project at any stage of the development should market conditions change and the project becomes unprofitable. In other words, the flexibility inherent in the investment decisions is valued using the RO technique, as opposed to not being so in the traditional ENPV analysis outlined above. This value is higher than the ENPV value because it assumes that management makes the right (highest NPV) choice in the event of a failure at each stage.

The ENPV of −£53,041 undervalues the project and could generally lead to a no-go decision for the blood glucose monitor project. By recognising that managerial flexibility exists and that investment funding is not committed until outcomes at different stages are known,
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the standard RO methodology recognises the value added to the project from the intervention of management and the flexibility to abandon the project to control downside risk and would rightly force managers to think twice about abandoning this project at an early stage. This added value is quantified by the option premium, which is given by the difference between the evaluation of the options framework and the ENPV framework, calculated as £57,757.

Thus, the additional value created by management intervention through risk management and abandoning the project at any of the four stages whenever market conditions become unfavourable is equal to £57,757. This additional value emerges because of the presence of volatility of the underlying asset. Hence, uncertainty is not seen as a bad thing but as an opportunity. The larger the amount of uncertainty, the greater the opportunity for value creation. Traditional ‘NPV’ methodologies are averse to risky and uncertain projects, whereas RO factor in uncertainty and assess the financial value of keeping an opportunity ‘alive’ at investment decision points within the NPD process.

An additional benefit of RO is that it allows managers to outline a phased approach to the strategy for the project that minimises risk by only making investments when downstream conditions are favourable.

Value of failure modes. Failing to recognise the additional value created by management intervention through risk management and abandoning a project is not the only source of error using a traditional discounted valuation technique. A second component often missing from traditional valuation techniques is the concept of ‘abandonment’ value. Quite often in an R&D scenario value accrues through other exploitation routes, even when the proposal may ‘fail’ a stage-gated decision. Typical exploitation routes for abandoned projects include:

- licensing patents or other IPR generated
- re-using the skills generated in other lucrative ventures
- re-using text generated on other proposals
- re-using contacts and alliances made in other proposals and ways
- adapting technology developed for other projects
- learning from mistakes and improving internal processes
- getting a place in critical bids or proposals because you have a key piece of technology.

Hence abandonment itself may produce positive cash flows. The value of the option to abandon is sometimes termed ‘salvage’ value. The option to abandon a project is formally equivalent to an American put option with the salvage value being equivalent to the exercise price. In the worked example described thus far, the RO model incorporates one type of abandonment option in the calculation by defining the value of the payoff as the highest of NPV of a particular stage or 0, in which case abandonment is exercised. By exploiting some of the routes above, the company can factor in the salvage value in the business model.

CONCLUSIONS

Following on from a consultation exercise with UK medical device manufacturers on existing capital budgeting practices, DCF techniques were highlighted as the most common way of assessing the financial value of projects and forming the basis project business plans. The main objective of this paper was to address some of the fundamental limitations of these techniques, namely the inability to account for the flexibility to change direction within a product development lifecycle,
and present alternative methodologies for valuation. Two models have been described, ENPV, which is an enhanced version of NPV analysis, and RO. Both models incorporate decision tree analysis and both are standard methodologies. ENPV analysis includes all costs from the development phase and subsequent revenues, weighted by their probabilities of occurrence and discounted back to the present, but it is flawed because, by ignoring the impact of economic/regulatory uncertainty, it excludes the flexibility inherent in the project. It also only uses a single discount rate during development whereas in practice project risk dynamically changes during the development. RO analysis seeks to overcome these deficiencies by ‘actively’ managing the development phase and placing a value on the flexibility to adapt to changing market conditions. RO are also evaluated in a risk-neutral world where the investor’s attitude to risk need not be considered. As seen from the analysis above, options inherent in the project add value to the project. In summary, RO analysis is a method of financial decision making that is more soundly based in modern finance theory than in standard techniques. It forces the practitioners to think hard about where the uncertainties exist and to attempt to quantify them. These are useful exercises in themselves even without the resulting option valuation.

To date, most practical application of Options Theory for research evaluation has been in the pharmaceutical and biomedical industries, for example, see Nichols. The drug development process contains multiple options, due to the different stages in this process. This is similar to the development of a medical device. That is, there is a discovery (or concept) process followed by phased trials (including clinical trials if necessary), regulatory approval and finally launch. Similar to the evaluation of a new drug, the value of a medical device at the concept stage is difficult to assess because it is subject to considerable uncertainty (technological, regulatory and market demand). The use of RO can provide a more accurate methodology for project appraisal together with a strategic plan. More work, however, needs to be done on the best way to model options within a product development environment and how best to capture data for RO modelling. Also one must account for the regulatory hurdles (and the costs incurred with these) as well as the fragmented reimbursement routes open to medical device companies. For example, in the UK, devices may be sold through the NHS Purchasing and Supply Agency, reimbursed on the UK Drug tariff or sold through private arrangements with individual trusts. The method of reimbursement will have a large impact on market size and cash flow predictions (as well as on volatility).

The issue of estimating the volatility appears to be a weakness in an RO valuation. In contrast with financial equity options, volatility can be very difficult to estimate for RO because RO are not traded and in many cases will not have historical rates of return associated with them. The value must reflect the uncertainties in the value of the underlying asset. It may be possible to estimate future market volume with its volatility by using appropriate statistics from similar ‘peer’ products. Medical device companies may use data from other similar products they or a representative group of companies have developed in the past. Many companies use the average volatility of publicly traded companies in their field; Merck uses the volatility of a sample of biotech stocks for its R&D assets. This however may lead to lower estimates of volatility as a company’s equity volatility is based on the
combination of a stream of cash flows from a portfolio of products and hence a ‘bad’ product cash-flow stream may be compensated by a ‘good’ product cash-flow stream within the same company.

In many cases there will be no historical or ‘peer’ volatility data as the medical device under development is considered as novel or new. In this case, one could make an educated guess\textsuperscript{22} based on information such as industry or market as a whole or use judgments made by senior management regarding the uncertainty of the project. Alternatively, one could run a sensitivity analysis with a range of assumptions to determine whether the choice of volatility alters the decision. Luehrman\textsuperscript{22} also suggests simulating the volatility by projecting a project’s future cash-flow and applying Monte-Carlo simulations to establish a probability distribution for the project returns and from this volatility can be calculated.

It is clear that estimating a volatility value for RO is certainly nontrivial. For some RO it may be impossible to estimate volatility correctly because of a lack of data or a lack of confidence in cash-flow projections, although this is the same for any DCF analysis. In this case, the insights and strategic analysis provided by an RO analysis are far more important than the actual quantitative result obtained by the analysis.

Finally, an additional hurdle to adopting an RO methodology within the company is that many managers can become committed to failing NPD projects and consequently are less likely to exercise an ‘abandonment’ option and terminate the projects after the go decision has been made.\textsuperscript{23}

There are still many issues to overcome if RO analysis is to be accepted for project valuation. In addition to those described above, the relative complexity of the technique may deter companies from using it. Further, very little work has been carried out on validating RO results for project valuation and this is required to command the confidence of decision makers. In practice, for project valuation, it is probably medical device companies with detailed and well-documented product development processes who are most likely to benefit from an RO analysis. For any medical device manufacturer, however, an understanding of product value through an RO ‘mindset’ creates the potential for a more informed dialogue around strategic management and product evaluation.

Acknowledgments
The authors acknowledge support of this work through the MATCH Programme (EPSRC Grant GR/S29874/01), although the views expressed are entirely theirs. The authors are also grateful to Professor Terry Young, Brunel University, for his valuable contribution to this paper.

References
Appendix A

If the current value of a project is $S$, then at the end of one period this can increase to $S_u$, with probability $p$ or decrease to $S_d$, with probability $1-p$. $u$ and $d$ are multipliers ($u>1$ and $d<1$).

\[ p = \frac{e^{rt} - d}{u - d} \quad (A.1) \]

where $r$ is the risk-free interest rate; $p$ the risk-neutral probability $u$ and $d$ are one-year multipliers and are given by

\[ u = e^{\sigma \sqrt{\Delta}} \quad (A.2a) \]
\[ d = e^{-\sigma \sqrt{\Delta}} \quad (A.2b) \]

where $\sigma$ is the volatility or annualised percentage standard deviation of the returns, $\Delta$ is the discrete time interval and is set to $\Delta = 1$. 