Risk evaluation in biotech management

An innovative approach by Professor Bellens and his team at Strategus

Professor Roel Bellens is co-founder of the financial management department at the European University College, Brussels and visiting professor at the universities of Louvain (Belgium), Groningen (The Netherlands), Sofia (Bulgaria), Saint Petersburg (Russia) and Stalowa Wola (Poland).

From 1978-1986 Roel held senior positions at Johnson & Johnson in Japan and the UK. He is presently managing director of Strategus, an independent research consultancy. A specialist in risk and value management, Prof. Bellens has published more than 100 articles and case studies and 3 books on value management, based on the integration of financial management, marketing and strategy. He has advised many multi-national companies including ABN-AMRO, Grolsch, GlaxoSmithKline, Hollandse Beton Groep (HBG), Koninklijke Volker Wessels (KVW), Roto Smeets De Boer, Nuon, Gasunie and TBI Holdings.

"Should we engage in a strategic alliance or go at it alone?"

Strategus is the commercial name of Risk Control and Finance Company NV, based in Antwerp where Professor Bellens and his team at Strategus have devised a set of tools for risk analysis in R&D environments.

Their team combines different disciplines such as finance, value & risk management, economics & simulations, to help bridge the gap between finance and strategic decision-making. Strategus aims to help management navigate through risks, uncertainties and complexities, with clear, client-centric solutions. Professor Bellens and his team use proprietary high level computing models to help management plan their decisions with a view to reducing their risk.

A risky business

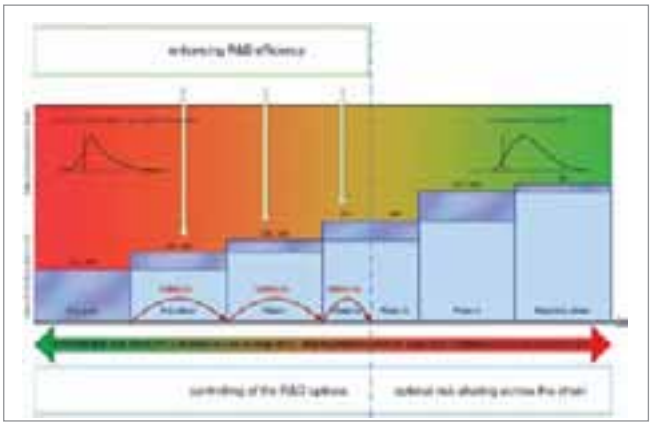
In a life sciences enterprise, in the early stages of development of new clinical biotech compounds, it is important that the right valuation methodology is used. Earlier in the decision process during pre-clinical, phase 1 and phase 2a, more options are still available to optimise value creation. These options disappear as the decision spiral is entered and the "bets" are on the table as if in a game of roulette. The business risks and decision points are not properly taken into account through using traditional valuation approaches such as NPVr.

Through modelling each client's unique decision process incorporating real options analysis, Strategus presents the relevant strategic options in an integrated decision "forest", where various "trees" represent various underlying value driver dynamics.

The real-life type of dilemma facing the commercialisation of a range of novel compounds might be described thus:

Which drug candidate(s) emerging from research should we develop ourselves? Should we engage in a strategic alliance or go at it alone? Should we out-licence our product(s) and (if so) on which terms? At which point in time can we choose another strategic route? What are the optimal outsourcing options according to the different financial characteristics? What is the best current estimate of company value that we should use in upcoming financing negotiations?

The work at Stategus in "Real Option Analysis" described here by Jef Versmissen, Partner & Business Development Director at Strategus, aims to surpass the "do-it-yourself" approach of commercially available real options spreadsheets where the user is left to his/her own devices to perform the entire analysis, as well as the flawed "black box" approach of much management consulting.



A graphical representation of some stages in real options analysis

Real options analysis - enhanced strategic decision making in R&D projects

Traditional income approaches to investment valuation implicitly assume that cash flow generation occurs according to an expected scenario and that management will remain passive once it has chosen a certain operating strategy. In reality the marketplace is dynamic and the realised cash flow pattern will differ from what the management expected when formulating the initial investment plan.

Professor Roel Bellens, Managing Director of Strategus

The traditional approach to value investment projects - exemplified by a Discounted Cash Flow analysis - has its origin in the valuation of risk-free securities. In this approach, risk factors are incorporated in the discount rate rather than in the cash flow stream itself.

Many practitioners favour this approach because it is assumed that adjusting discount rates is much easier than forecasting certainty-equivalent cash flows while still producing relevant results.

The interaction between important elements of the strategic decision process towards an optimal investment policy is overlooked in this approach: the investment is at least partially irreversible ("sunk"); future rewards are largely uncertain; and management almost always retains some flexibility in timing actual investment decisioins. The pitfall of the DCF rule is the assumption of "now-or-never" decisions if the investment is irreversible, effectively eliminating all options available to management

Note that a real options analysis of investment decisions does not imply discarding all traditional approaches; ROA should primarily be considered in order to quantify strategic managerial flexibility.

Dynamic management of R&D projects and portfolio's using real options

The value of real options provides important insights into the value of flexibility. A real options methodology offers management the ability to incorporate risks and uncertainties, and not merely passively submit to changing

market circumstances.

Decision tree analysis for example has difficulty in capturing the changing risk profile of altering operating strategies. An approach based on expected cash flows assuming passive management has proven imperfect especially in those circumstances where uncertainty prevails and management acumen may add considerable value, such as in the pharmaceutical and biotechnology industry.

"a strong tool to optimise the transaction structure"

The greater the uncertainty within an R&D project, the greater the value of an opportunity and the greater the incentive to wait and keep the opportunity alive rather than exercise it immediately (It is possible to incorporate competitive pressure with game-theoretic elements that can potentially alter the previous statement). Uncertainty and flexibility are key determinants of the value of an asset and call for an expanded valuation criterion. The optimal decision based on such expanded criterion, may well be to accept projects with negative present values of expected cash flows, if this is offset by a suitable larger option premium – the value of the real option.

Optimising joint R&D or licensing agreements through real option analysis

In fact, it is already well known that the NPV rule may lead to the wrong conclusions: it is incorrect that one should always invest when revenues are above long run average costs, or abandon the project the moment the price drops below variable costs. True investment hurdle rates differ significantly from what one would expect in a classical model. When different parties are concerned in an investment decision, matters are further complicated. Agreements must carefully calibrate between current and anticipated risk in projects where the respective parties might have different expectations with regard to fixed cash flows (e.g. up-front payments or contractual R&D compensation…) and variable compensation structures (e.g.royalty rates on future revenues).

Typically the licensor has an option at multiple instances whether to make a predetermined milestone payment to continue the alliance or terminate the alliance instead because of unfavourable market conditions and/or internal budget constraints.

Dynamic programming in real options analysis controls for uncertainty over the lifetime of a project by breaking up the entire sequence of decisions into two components: the immediate decision and a function that expresses the consequences of all subsequent decisions, conditional on the current decision. In so doing, the method efficiently evaluates all of the possible future evolutions to look for the optimal transaction structure at each point in time.

Interrelationships among R&D projects as a solution to the researchers' dilemma

While budget contstraints may make the acquisition, implementation or divesture of specific projects mutually exclusive, a firm that acquires or divests projects should not evaluate these projects on a stand-alone basis. The proper balancing of project interactions and various constraints requires a portfolio approach: synergy and learning effects and non-divisibility issues, among others, are to be considered when ranking project opportunities.

Conclusion

Real option analysis is more than a valuation methodology; it explicitly invites management to "to do something" with the flexibility in the firm's project portfolio. Real options can manage the inherent uncertainty in investing in a manner more traditional methodologies can not. Management can systematically identify and evaluate the options in a project to enhance the value of the project, by taking advantage of the upside potential while avoiding downside risk.