

Assess and manage risk. Make better decisions. Create value.



White Paper 3

Case Studies: Tough Decisions in the Life Sciences Industry

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KROMITE, LLC

Our Team – Your Resource

KROMITE was founded ten years ago to provide independent and unbiased support for tough decisions in the life sciences industry. Our team, located in US, Canada and Europe, possesses unparalleled expertise in scenario analysis and decision-making. From years of working for and with biotech, medical device, agricultural and pharmaceutical companies, our consultants command intimate knowledge of the terminologies, organizational roles and responsibilities, product research and development processes, common deal term structures, and organizational decision making processes, which allows you to rely on us as a partner and external expert.

We achieve measurable results as demonstrated in these Case Studies:

1. Assessing risk and value of a project with multiple options
2. Accounting for uncertain target product profiles (TPPs) of competition
3. Assessing an in-licensing opportunity

Case Study 1: Assessing a Project with Multiple Options

Situation: A pharmaceutical product in development had a number of choices available to it: number and order of indications, number of “back-up” and “second generation” compounds, parallel or serial development in US, Europe, and Japan. The sheer number of choices was overwhelming the project team and slowing down the project.

Key Decisions					
Strategic Options	Target Indications	Order of Indications	# of Backups	# of 2 nd Generation	Global Development
Cost / Risk Conscience	Indication 1 Alone	None	None	None	US / EU
Speed to Market	Indication 2 Alone	Indications 1 & 2 in Parallel	Backup 1	2 nd Generation 1	US / EU / JAPAN Serial
Global Launch	Indications 1 & 2	Indication 1 then 2	Backup 2		US / EU / JAPAN Parallel
		Indication 2 then 1	Backups 1 & 2		

Figure 1A. Strategy Table – Illustrative.

Solution: All key decisions were identified and possible options for each decision were outlined. By choosing three strategies that linked potential future options, the choices were narrowed to:

“cost/risk tolerance”, “speed to market,” and “global launch” (Figure 1A).

Value, cost, timing, and risk of each strategy were assessed and multiple

scenarios were examined to test hybrid strategies. The key factors that made one strategy more valuable than another were determined through sensitivity analyses (Figure 1B).

Outcome: A hybrid strategy was chosen. It increased the value of the project by

30% while managing the risk through partial development of back-up compounds. The project team focused its efforts on the value-adding activities resulting in a six-month acceleration of the clinical program.

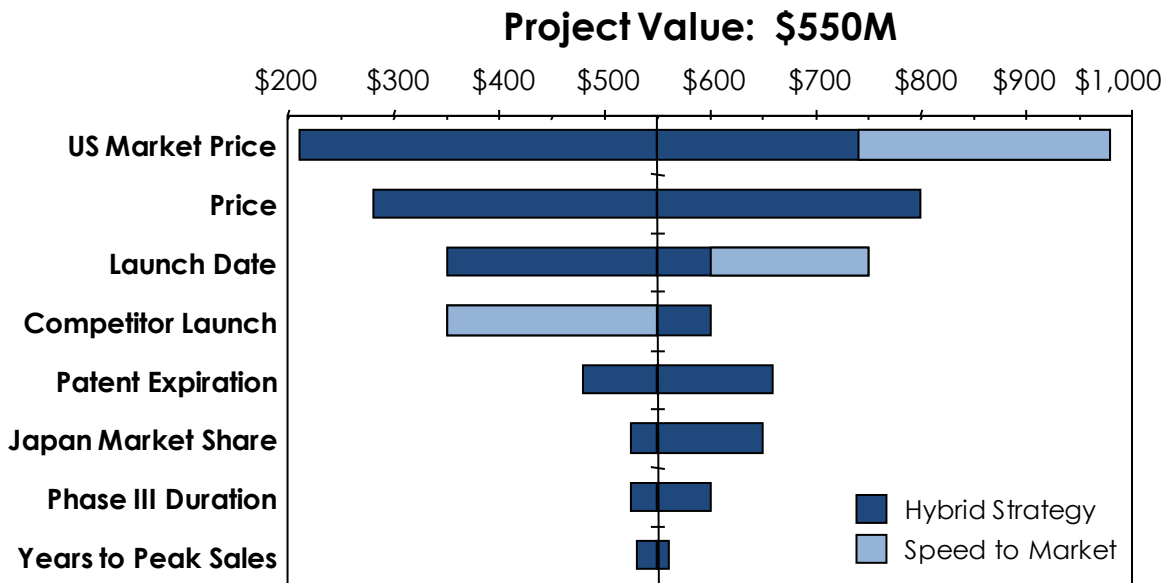


Figure 1B. Sensitivity Analysis to Strategic Options – Illustrative.

Case Study 2: Accounting for Uncertain TPPs of Competition

Situation: A client required a sales forecast that incorporated the uncertainties in a competitor’s launch date and the profile of the product under consideration.

Solution: A market forecast was developed encompassing all marketed products, their patent expiration and generic entries. The launch dates of all products were captured as uncertainties.

Target product profiles were developed for key competitive pipeline products. Multiple potential product profiles were developed for the product under consideration along with the probability of achieving them. A probabilistic model was developed incorporating the launch of all products along with their probability of reaching the market.

Historical uptake rates as well as products’ features were used to estimate market penetration rates and market share (Figure 2A). Sensitivity analysis was used to identify the impact of all factors on sales.

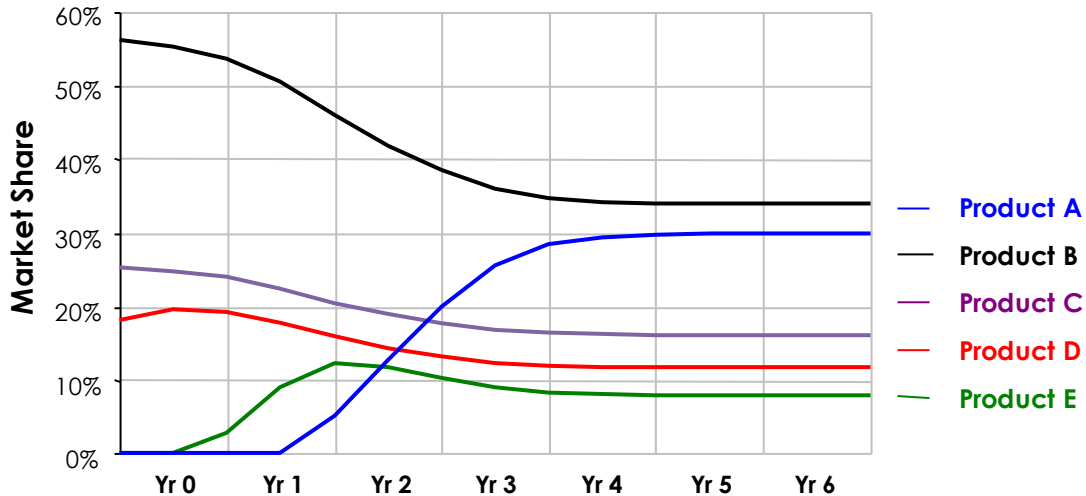


Figure 2A. Market and Product Forecast – Illustrative.

Outcome: The analysis provided multiple sales forecasts under different scenarios (Figure 2B). The forecasts identified the potential upsides and downsides given

the uncertain future events. The analysis also identified the key drivers of value and risk for the project, which was used to focus future market research studies.

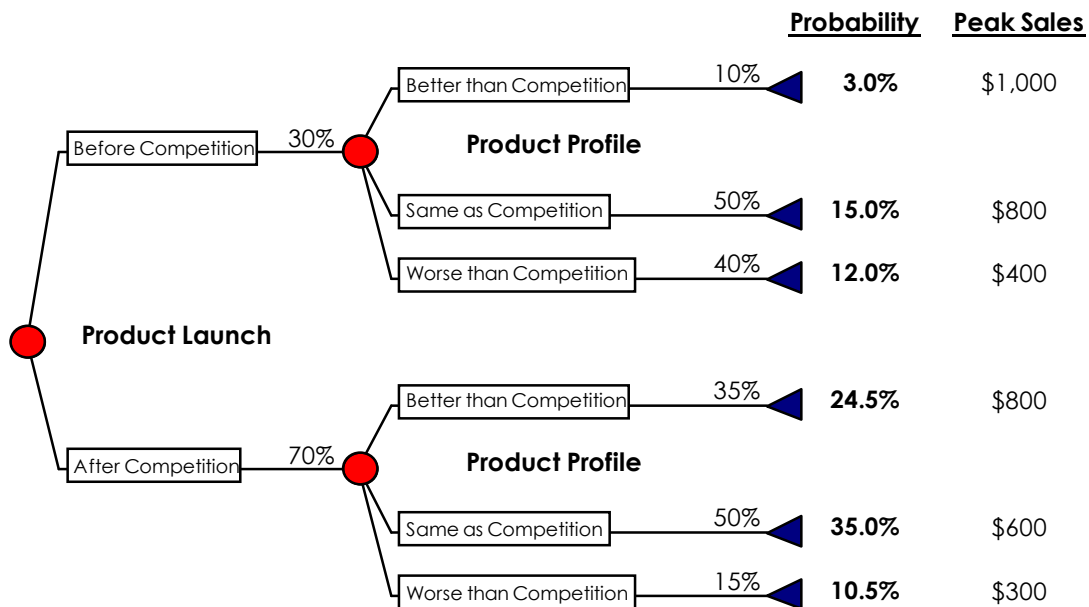


Figure 2B. Sales Forecast Decision Tree – Illustrative.

Case Study 3: Assessing an In-Licensing Opportunity

Situation: A company was evaluating an in-licensing candidate that was similar to an internal project. Both were going after an attractive market. The company wanted to know if they should license this product given that the internal analysis had given the candidate a low value.

Solution: Risk and value of both internal and external projects were assessed along with all possible options available. It was discovered that the internal

analysis had only examined the scenario where both projects were successful. Closer examination showed that most likely only one, or none, of the products would reach the market and that the in-licensing opportunity actually increased the odds of the company's presence in the market (Figure 3).

Outcome: The company went forward with a licensing agreement. The in-licensing improved the odds of having at least one compound in the market from 25% to 47.5%. The project also added an additional expected \$59M to the company's portfolio.

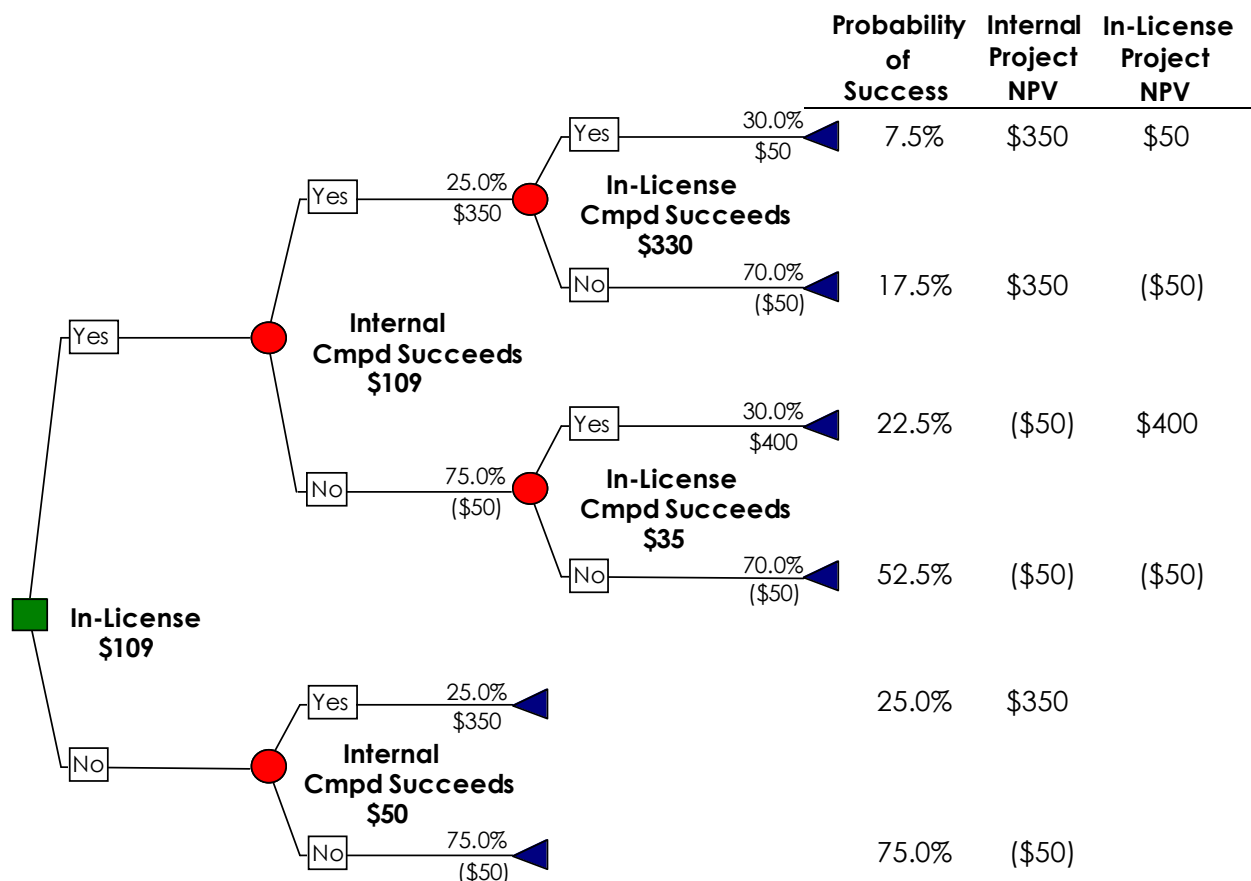


Figure 3. Decision Tree – Illustrative. Overall NPV with an in-licensed compound is \$109M, and overall NPV without an in-licensed compound = \$50M. Decision to in-license is supported based on the higher NPV.

In Summary

Maximizing value, managing risk, and aligning decisions with company values requires an integrated decision-making process – This is KROMITE's strength. We work with clients to develop high quality research and development, licensing and commercialization strategies through a better understanding of value in the context of risks and uncertainties.

We provide a measure of value that includes both financial and non-financial components. Utilizing this comprehensive methodology allows clients to consider alternatives that may not have been previously considered due to financial metrics alone.

We look forward to meeting with you at the **2013 Life Science CEO Forum** and discussing how we can assist you in the areas of:

- **Strategy:** New Product Development, Therapeutic Area, Indication Sequencing, Portfolio, Licensing
- **Portfolio Management:** Optimization, Gap Analysis, Prioritization
- **Multiple Objective Decision Analysis**
- Modeling of Complex Systems: R&D Process, Resource Allocation, Open Innovation, Economic Modeling, Simulation & Analysis
- **Benefit-Risk Analysis:** Multiple Objectives Approach, Multiple Stake Holders
- **Supporting Services:** Facilitation, Elicitation, Asset Valuation, Risk Assessment

Abbreviations

- NPV = Net Present Value, a sum of discounted cash flows over a stated time horizon
- TPP = target product profile

About KROMITE

KROMITE is a leading strategic advisory firm that specializes in the application of decision science to help clients make strategic decisions, manage risk, and create value. KROMITE was founded in 2003 to provide independent and unbiased support for tough decisions in the life science industry.

Our team, headquartered in New Jersey and located throughout North America and Europe, possesses unparalleled expertise in scenarios analysis and decision making. From years of working for pharmaceutical, biotech, medical device and agricultural companies, our team commands intimate knowledge of tools, terminologies, organizational roles & responsibilities, R&D processes, common deal term structures, and organizational decision making processes, which allows our clients to rely on us as a partner and external expert.

For more information about KROMITE, please call us at +1 (267) 983 6305, email us at info@KROMITE.com, or visit our website at www.KROMITE.com.

About the Author

Jack Kloeber PhD, Principal

Jack was a Senior Partner at KROMITE for 5 years and is now Principal. Jack is a retired US Army Lieutenant Colonel with experience in R&D portfolio management, decision analysis, modeling and simulation, technology selection, and strategy development. Jack was head of Portfolio Management for Bristol-Myers Squibb and, more recently, head of Portfolio Management for J&J Pharma Services, where he coordinated the portfolio management efforts across multiple R&D and marketing operating companies. He received his Ph.D. in Economic Decision Analysis from Georgia Institute of Technology and Masters in Industrial Engineering from Lehigh University. Jack is a board member and Fellow of the Society of Decision Professionals, a member of the Decisions Analysis Society, and a 20-year member of the Institute for Operations Research and the Management Sciences (INFORMS).

