projects D, E, F, H, J, M, do these first! Then, leave the option open to execute the remaining projects (I, K, T) if management decides to pursue P3 later.

CASE 7: BIOPHARMACEUTICAL INDUSTRY—VALUING STRATEGIC MANUFACTURING FLEXIBILITY

This case study was contributed by Uriel Kusiatin, principal and cofounder of 2Value Consulting Group (urielk@twovalue.com), a New York–based management consulting firm that applies advanced financial evaluation and decision analysis techniques to help biopharmaceutical companies significantly improve the way they make and execute strategic decisions. Specifically, 2Value utilizes real options, Monte Carlo simulation, and optimization techniques to evaluate R&D portfolio decisions, licensing opportunities, and major capital investments. 2Value is a strategic partner of the author's firm, Real Options Valuation, Inc. Mr. Kusiatin holds an MBA from the Wharton School and a BSc in industrial engineering from The Engineering Academy of Denmark.

Making decisions on significant investments in manufacturing capacity is a challenging proposition. Biopharmaceutical manufacturing and operations executives are often required to make difficult decisions—decisions that may have significant impact on their company's ability to successfully compete in a complex and highly uncertain business environment.

One of the biggest challenges facing these executives is securing manufacturing capacity for products that are under development and years away from launch. They face a choice between multiple alternatives that include building internal capabilities, outsourcing these to a Contract Manufacturing Organization (CMO), or a combination of the two.

These decisions involve significant capital investments as well as the opportunity cost of allocating funds away from other important initiatives. An internal solution may take four to six years and cost up to $500 million to implement, while there is no guarantee that an outsourced solution will be available when needed, or be sufficiently cost-effective and flexible to meet the needs of the company.

Sizing capacity needs is also challenging. Technology risk associated with biopharmaceutical drug development efforts is high. The probability of a drug candidate in preclinical trials reaching the market is on average less than 20 percent. Market assumptions regarding price, demand, and competition may change dramatically during the lengthy development process and require different capacity than initially anticipated. Build too much and the company

will be left with an underutilized asset while trying to identify ways to recoup wasted investment dollars that could have been better utilized elsewhere. Build too little and the company may lose substantial revenue opportunities. Given the risks (and opportunities) inherent in drug development,

- How should manufacturing executives choose the best strategy such that risks are sufficiently mitigated while opportunities are taken full advantage of?
- What can management do to increase its decision-making confidence and improve its capacity-planning capabilities?

The following case study explores how a real options approach can be used to help value and structure strategic investment decisions in a pharmaceutical manufacturing context.

Traditional Valuation Methods and Suboptimal Decisions

Planning for manufacturing capacity typically begins very early in the product development process, often toward the end of preclinical trials or the beginning of Phase I. The key driver used to formulate capacity decisions is a forecast of product demand and anticipated product launch date. Based on these and other assumptions, planners develop a basic timeline that typically incorporates lead times for design and engineering, construction of facility and installation of equipment, and validation and regulatory approval. In addition, they develop initial cost estimates for various alternatives.

Planners must consider a wide range of issues. Typical questions arise:

- What are the available alternatives/strategies that can meet requirements?
- What types of uncertainties from a commercial and product development perspective should be considered?
- How can we secure the appropriate amount of capacity while maintaining the flexibility to expand or contract should business conditions change?
- What is the optimal strategic pathway when strategies have different investment levels, timing, and impact on project value?

For example, suppose a biopharmaceutical company has a product in the preclinical phase of development. The company is initially targeting its most lucrative market—the high-price/low-volume primary market. Marketing has also identified a secondary market—the low-price/high-volume market—that the company may consider expanding into given the right conditions.

Supplying the secondary market with a product will require a significant expansion of capacity.

The company's operations planning group has conducted a feasibility study of various manufacturing capacity strategies and has narrowed the number of alternatives to the following (simplified for illustrative purposes):

Strategy A: Retool an existing facility for launch capacity—commit capital to build new facility to accommodate both primary and secondary markets once the drug has successfully completed the pivotal Phase II clinical trial studies. New facility is expected to be online three years after the product receives FDA approval.

Strategy B: Build a new modular facility—install capacity needed for launch and expand with additional capacity (additional equipment within existing facility) once the drug successfully completes the pivotal Phase II clinical trial studies. Capacity to supply primary and secondary markets is expected to be online with product approval.

Traditional methods used to justify these types of investments are usually based on the discounted cash flow (DCF) model's net present value (NPV) approach.

Given the NPV approach used as seen in Table 11.32, management should focus on the primary low-volume/high-price market only and pursue Strategy A as it provides the highest NPV of both alternatives.

But is this really the optimal strategy?

The problem with the traditional NPV approach is that it is static, that is, it assumes that demand forecasts (and other assumptions driving cash flows) can be projected with 100 percent certainty into the future and that investments are precommitted no matter what happens (i.e., product fails a clinical trial phase, secondary market turns out to be unprofitable). But how certain can planners be of their assumptions when in reality:

- Market factors impacting demand such as competitor moves, pricing and reimbursement, regulatory, and so forth, may change dramatically when the product finally launches.
- Uncertainty increases over time, that is, the further in the future the forecast goes, the more uncertain the forecast. This is especially true when product launch is years away.
- The probability of launching due to product development uncertainty is low—few drugs actually make it to market.

The many uncertainties facing biopharmaceutical decision makers can be described using Monte Carlo simulation Risk Simulator software. These

TABLE 11.32 Manufacturing Capacity Strategies Using Traditional Valuation Approach

	PV of Cash Flow		Investment		Time to Market		NPV	
	Primary Market	Secondary Market	Initial Capacity	Expansion Capacity	Primary Market	Secondary Market	Primary Market	w/Secondary Market
Strategy A—Retool existing facility and expand with new facility	$1,131	$186	$70	$450	Year 9	Year 12	$1,070	$874
Strategy B—Build new modular facility and expand capacity with additional bioreactors	$1,131	$283	$400	$50	Year 9	Year 9	$782	$1,022

uncertainties and their impact on NPV can then be captured and quantified, that is, upside opportunities as well as risks can be identified so that they can be better managed. Real options, as opposed to traditional valuation methods, allows management to value its inherent ability to exploit upside uncertainty while mitigating downside risk.

Valuing Strategic Manufacturing Flexibility Using a Real Options Approach

In reality, management does not have to precommit to making investments before some level of uncertainty clears up, that is, it has the flexibility to make midcourse corrections when better information becomes available.

Manufacturing executives have numerous options at their disposal. For example:

- Build a pilot plant as an option to develop process technology capabilities while outsourcing manufacturing for large-scale production to a partner.
- Buy an option to expand capacity should new opportunities develop.
- Buy an option to sell off excess capacity or use unfinished facilities should business conditions change.
- Use contract manufacturing as a backup/expansion option.
- Abandon/delay facility construction as a response to R&D failure/delay.

In our example, expanding capacity in year 3 is an option contingent on successful completion of Phase II clinical trials and an NPV greater than 0; that is, the decision to commit resources to expansion will happen in year 3 based on better information available at that point in time as seen in Figure 11.51. In addition, the staged nature of manufacturing capacity investments can be linking to key R&D milestones. These investments can be viewed as a series of compound options to abandon the project at any time should NPV become unattractive as seen in Figure 11.52. Obviously, if the R&D effort fails at any point, management can abandon the project and discontinue any further investments.

Volatility of market-based cash flows for both primary and secondary markets was estimated at 40 percent using Monte Carlo simulation with Risk Simulator and applying the Logarithmic Present Value Approach (see Appendix 7A). A market expansion factor was calculated for each strategy to account for the additional cash flows derived from the secondary market. Strategy A's expansion factor was 1.16 times the primary market, while Strategy B's was 1.25. The reason for this difference is the timing of when expansion capacity becomes available. Strategy A's expansion capacity is expected to be online in year 12—it must be built from scratch. Strategy B's expansion capacity is expected to be online in year 9 when product is expected to

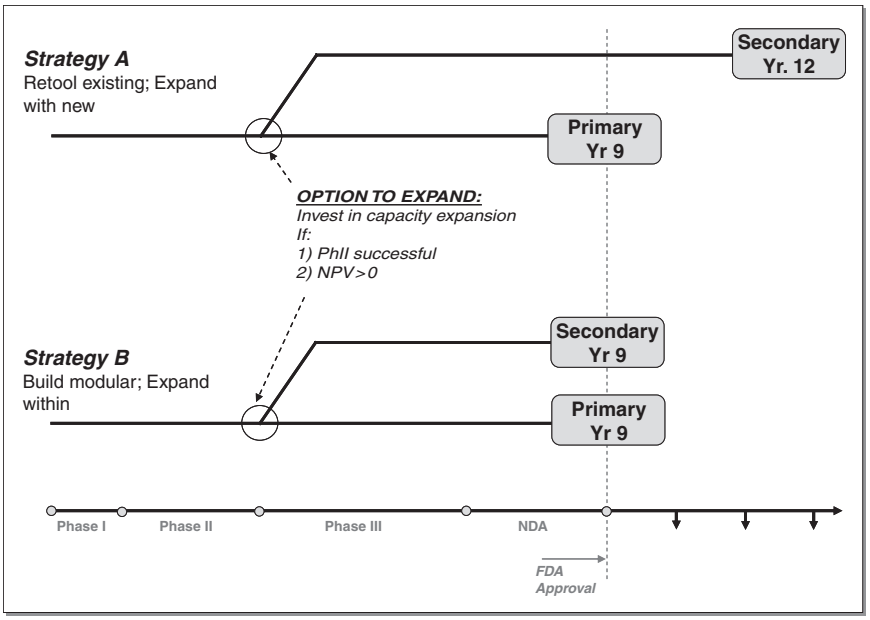


FIGURE 11.51 Strategy Tree for Two Competing Strategies

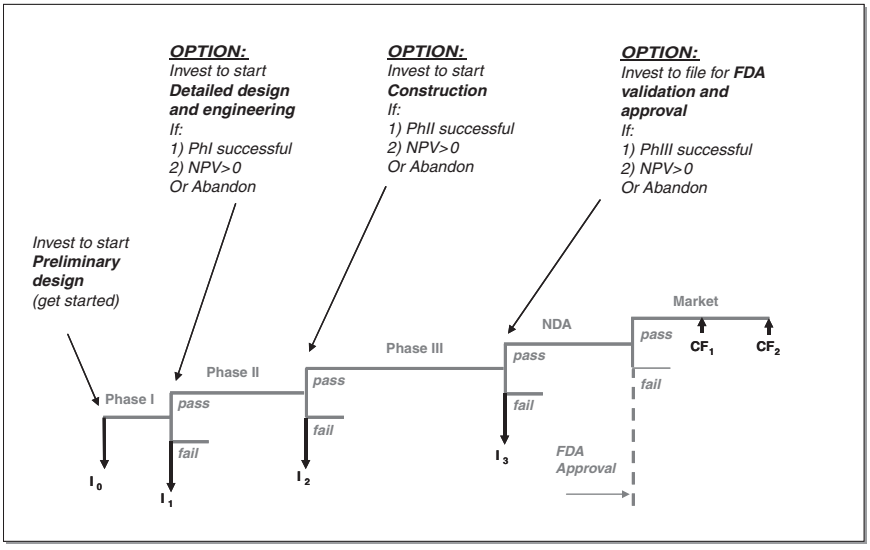


FIGURE 11.52 Linking Manufacturing Capacity Investment Decisions to R&D Clinical Trial Outcomes

launch—additional equipment/suites can be installed and validated in existing buildings to coincide with product launch.

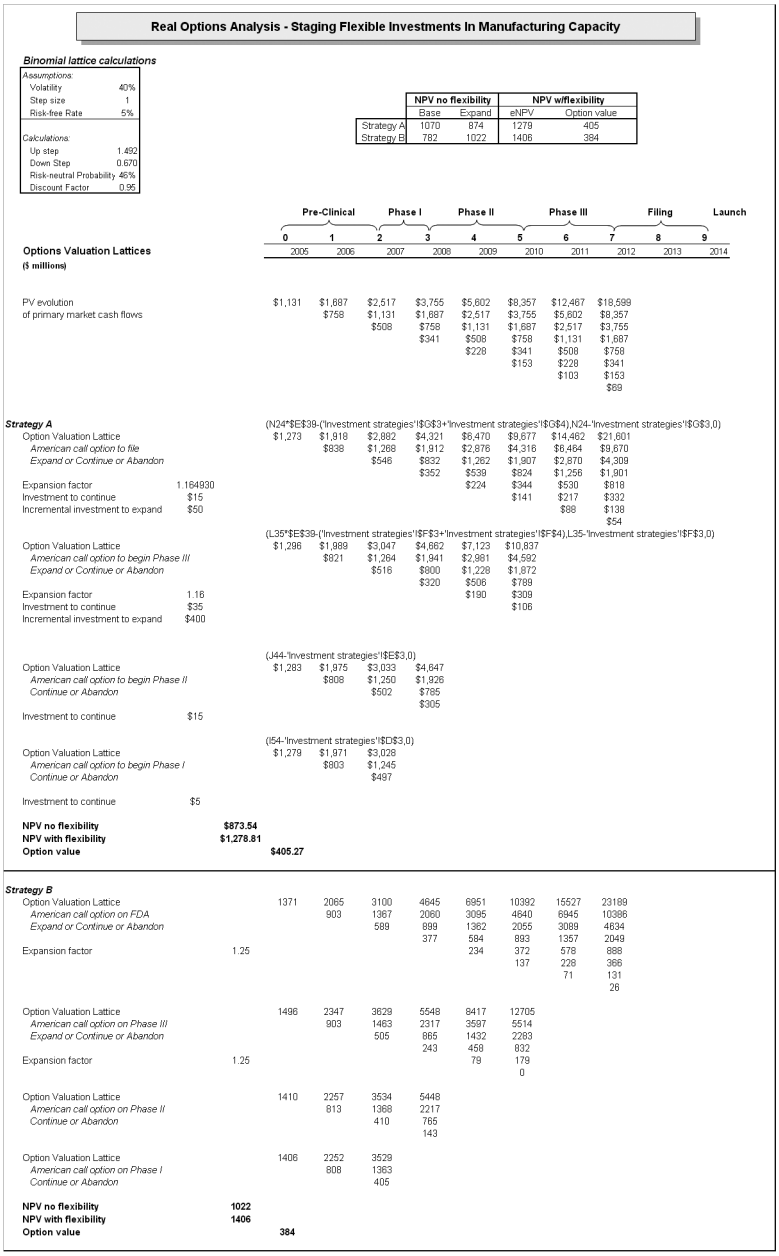
A series of compound options was constructed, each option dependent on the preceding option. The options to start Phase III and FDA filing and validation are chooser options, that is, the option to expand capacity to manufacture to the high-volume/low-price secondary markets, or continue with existing capacity plans to manufacture to the low-volume/high-price primary markets, or abandon the project altogether. For each scenario, NPV is calculated for each option, that is, expand, continue, or abandon. Whichever option provides the highest NPV is the option that will be chosen for that particular scenario. The options to start Phase II and Phase I are basically to continue investing or exit. The decision to continue will depend primarily on the outcome of clinical trials and perceived market value of the opportunity at that point in time.

The resulting NPV of these compound options includes the value of expanding, continuing, or abandoning further investments in capacity only if the NPV in a given scenario is positive or warrants expansion investments (i.e., no precommitment). The option value or value of having this flexibility is the difference between the calculated NPV and the static NPV, that is, the NPV that does *not* account for uncertainty or flexibility (Figure 11.53).

Using a real options approach in our example causes our decision to change—strategy B becomes the optimal strategy. With strategy B, management will commit less total capital for base and expansion capacity while being able to bring expansion capacity (should they need it) to the market with product launch (due to the modular nature of facility layout). Strategy A requires more capital investments in expansion capacity—a new facility must be built from scratch—and due to the build-out lead times, expansion capacity will only be available three years after product launch. That said, Strategy A has more option value, that is, the flexibility to expand, continue, or abandon is more valuable. A greater portion of total investments is deferred until uncertainty is cleared up, post–Phase II. The option to build a new (and costly) facility if, and only if, it makes business sense has value as seen in Table 11.33.

The results seen in Figure 11.53 ($1,279) can be calculated using the MSLS software as seen in Figures 11.54 and 11.55. The former illustrates the same results with a 7-step lattice while the latter illustrates taking the same analysis to 70 steps and beyond, to check for convergence of the results. It would seem that the analysis results are robust and can be simply computed using the MSLS.

This case study illustrates how a real options approach can help managers make better decisions regarding significant investments in manufacturing capacity. It should be mentioned that this approach can be utilized for significantly more complex decisions. In addition, the uncertainties described and



Real Options Analysis - Staging Flexible Investments In Manufacturing Capacity

Binomial lattice calculations

Assumptions:	
Volatility	40%
Step size	1
Risk-free Rate	5%
Calculations:	
Up step	1.492
Down Step	0.670
Risk-neutral Probability	46%
Discount Factor	0.95

	NPV no flexibility		NPV w/flexibility	
	Base	Expand	eNPV	Option value
Strategy A	1070	874	1279	405
Strategy B	782	1022	1406	384

		Pre-Clinical		Phase I		Phase II		Phase III		Filing	Launch
		0	1	2	3	4	5	6	7	8	9
Options Valuation Lattices		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
($ millions)											
PV evolution of primary market cash flows		$1,131	$1,687 $758	$2,517 $1,131 $508	$3,755 $1,687 $758 $341	$5,602 $2,517 $1,131 $508 $228	$8,357 $3,755 $1,687 $758 $341 $153	$12,467 $5,602 $2,517 $1,131 $508 $228 $103	$18,599 $8,357 $3,755 $1,687 $758 $341 $153 $69		
Strategy A		(N24*$E$39-('Investment strategies'!$G$3+'Investment strategies'!$G$4),N24-'Investment strategies'!$G$3,0)									
Option Valuation Lattice		$1,273	$1,918	$2,882	$4,321	$6,470	$9,677	$14,462	$21,601		
American call option to file			$838	$1,268	$1,912	$2,876	$4,316	$6,464	$9,670		
Expand or Continue or Abandon				$546	$832	$1,262	$1,907	$2,870	$4,309		
					$352	$539	$824	$1,256	$1,901		
Expansion factor	1.164930					$224	$344	$530	$818		
Investment to continue	$15						$141	$217	$332		
Incremental investment to expand	$50							$88	$138		
									$54		
		(L35*$E$39-('Investment strategies'!$F$3+'Investment strategies'!$F$4),L35-'Investment strategies'!$F$3,0)									
Option Valuation Lattice		$1,296	$1,989	$3,047	$4,662	$7,123	$10,837				
American call option to begin Phase III			$821	$1,264	$1,941	$2,981	$4,592				
Expand or Continue or Abandon				$516	$800	$1,228	$1,872				
					$320	$506	$789				
Expansion factor	1.16					$190	$309				
Investment to continue	$35						$106				
Incremental investment to expand	$400										
		(J44-'Investment strategies'!$E$3,0)									
Option Valuation Lattice		$1,283	$1,975	$3,033	$4,647						
American call option to begin Phase II			$808	$1,250	$1,926						
Continue or Abandon				$502	$785						
					$305						
Investment to continue	$15										
		(I54-'Investment strategies'!$D$3,0)									
Option Valuation Lattice		$1,279	$1,971	$3,028							
American call option to begin Phase I			$803	$1,245							
Continue or Abandon				$497							
Investment to continue	$5										
NPV no flexibility	**$873.54**										
NPV with flexibility	**$1,278.81**										
Option value		**$405.27**									
Strategy B											
Option Valuation Lattice		1371	2065	3100	4645	6951	10392	15527	23189		
American call option on FDA			903	1367	2060	3095	4640	6945	10386		
Expand or Continue or Abandon				589	899	1362	2055	3089	4634		
					377	584	893	1357	2049		
Expansion factor	1.25					234	372	578	888		
							137	228	366		
								71	131		
									26		
Option Valuation Lattice		1496	2347	3629	5548	8417	12705				
American call option on Phase III			903	1463	2317	3597	5514				
Expand or Continue or Abandon				505	865	1432	2283				
					243	458	832				
Expansion factor	1.25					79	179				
							0				
Option Valuation Lattice		1410	2257	3534	5448						
American call option on Phase II			813	1368	2217						
Continue or Abandon				410	765						
					143						
Option Valuation Lattice		1406	2252	3529							
American call option on Phase I			808	1363							
Continue or Abandon				405							
NPV no flexibility	**1022**										
NPV with flexibility	**1406**										
Option value		**384**									

FIGURE 11.53 Real Options Analysis—Compound Chooser Options

TABLE 11.33 Manufacturing Capacity Strategies—Real Options Valuation Approach

	PV of Cash Flow		Investment		Time to Market		NPV		
	Primary	Secondary	Initial	Expansion	Primary	Secondary	wo/flexibiity	w/flexibility	Option Value
Strategy A—Retool existing facility and expand with new facility	$1,131	$186	$70	$450	Year 9	Year 12	$874	$1,279	$405
Strategy B—Build new modular facility and expand capacity with additional bioreactors	$1,131	$283	$400	$50	Year 9	Year 9	$1,022	$1,406	$384

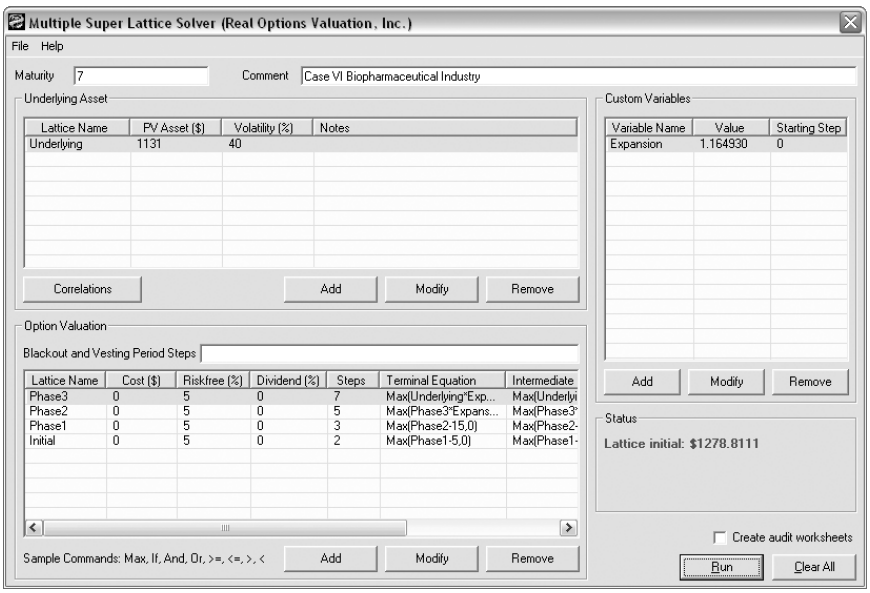


FIGURE 11.54 Multiple SLS Solution (Seven Steps)

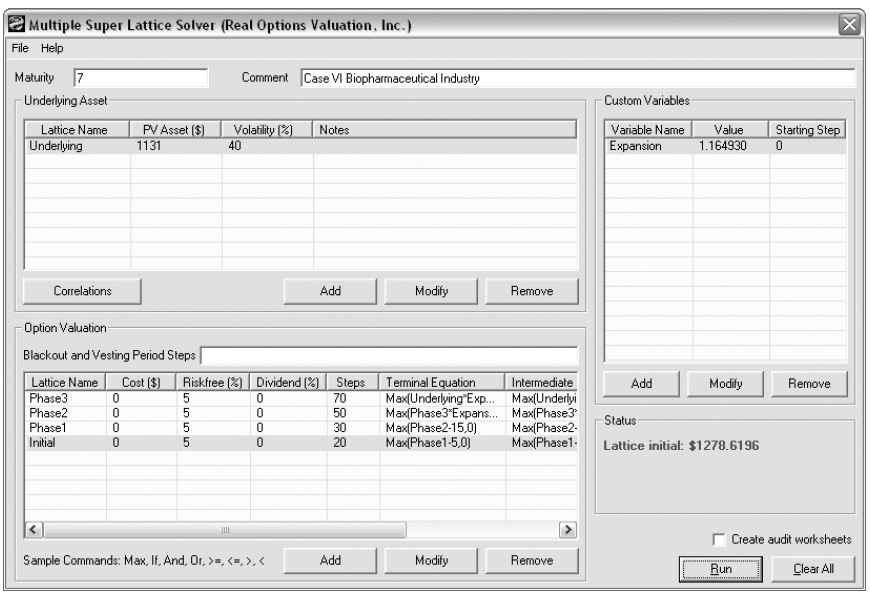


FIGURE 11.55 Multiple SLS Solution (70 Steps)

incorporated in our example are market driven. It is important to also incorporate the probability of technical success, that is, the probability of successfully getting a drug to market. R&D clinical trial success rate probabilities can easily be incorporated into the Monte Carlo simulation.

Implementing a Real Options Approach

The real options approach just described incorporates a learning model, such that management makes better and more informed strategic decisions when some levels of uncertainty are resolved through the passage of time. It also forces management to focus on key decision points or milestones, such as when do we need to make key investment commitments? What are our options at a given point in time that allow us to take advantage of opportunities while reducing risk? What is the cost of waiting or deferring a decision?

This approach sets a premium on obtaining better information before making important decisions. It values flexibility (and identifies the cost of this flexibility) while improving decision makers' risk management capabilities. As such, it can and should be linked to project management execution because value can only be captured if the option is executed optimally.

A real options approach is straightforward to implement and is based on existing inputs and valuation methodologies already used in most companies. Real options analysis adds an additional step to the existing NPV analysis by quantifying the value of the options available to management.

CASE 8: ALTERNATIVE USES FOR A PROPOSED REAL ESTATE DEVELOPMENT—A STRATEGIC VALUE APPRAISAL

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Introduction

It is not uncommon in real estate development for an investor to hold a property where alternative land development uses may be available, subject to