

This article investigates the staging option to analyze an existing case study that involves the potential licensing of a drug compound that is in development. It demonstrates how options analysis is a useful tool in adding insight to the decision making process when conventional valuation methods are not decisive.

## The Staging Option and Drug Development

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### Introduction

**R**esearch and Development (R&D) projects are routinely evaluated to determine if the projects are feasible and worthy of continued funding. Most R&D organizations have more ideas than they have resources to fund them so projects must compete for available resources, including money and talent. A widely used technique for evaluating projects is Discounted Cash Flow (DCF). In this method, the Net Present Value (NPV) is determined by discounting forecasted future cash flows by a required rate of return, as shown in equation 1.

$$NPV = -I_0 + \sum_{T=1}^n \frac{FV_T}{(1+r)^T} \quad (\text{Eq1})$$

where

- $I_0$  is the original investment
- $FV_T$  are the future cash flows
- $r$  is the interest rate
- $T$  is the time increment

The discounted cash flow method is widely used to determine the value of projects, and has been widely embraced by industry. Despite its wide use, discounted cash flow biases evaluators toward conservative conclusions. Good ideas are sometimes not pursued because the method provides an NPV that is often too low.<sup>1</sup> Management usually has flexibility during the course of R&D projects, and this flexibility is

not accounted for in the DCF technique.<sup>2</sup>

Projects with NPVs that are very high are considered good investments from the DCF perspective. Projects with NPVs that are negative are generally abandoned because they will not deliver the required return. Projects with NPVs close to zero require significant additional effort to determine if such projects should be funded or abandoned. Real options analysis can be used to add insight to the funding decision, especially when DCF analysis finds an NPV that is close to zero. Real options analysis offers an alternative that determines a value for managerial flexibility and provides an Expanded Net Present Value (ENPV).

### Options

A financial option is an asset that gives the owner the right, without an obligation, to buy or sell another asset (such as a quantity of corporate stock) for a specified price at or before some specified time in the future. A real option is a potential investment, such as a project, that is funded only if the firm decides it is in its best interest to do so. The option to invest in a project (or not to invest) has value. In real options analysis, the option to invest in the project creates an ENPV, which is defined as:<sup>3,4</sup>

$$ENPV = NPV + \text{Option Value} \quad (\text{Eq2})$$

When NPV is quite large, the option value will not have a significant impact on the decision: the NPV signals that the project is worthy of investment. When NPV is very negative, even the best option values will not be large enough to create a positive ENPV, and the project should not be pursued. If the future cash flows are known with certainty, then the DCF technique should be used. Real options have their best use under conditions of uncertainty, and where management has the ability and the

Variable	Financial Options (such as stock options)	Real Options (such as projects)
T	Time to expiration	Time to expiration
r	Risk-free interest rate	Risk-free interest rate
X	Exercise price	Implementation cost
S	Stock price	PV of future cash flows
$\sigma$	Volatility of stock price movement	Volatility of future returns

Table A. Option variables.

Phase	Average Chance of Success, %		
	Average <sup>(14)</sup>	Small Molecule <sup>(10)</sup>	Large Molecule <sup>(15)</sup>
Preclinical	35	...	...
Clinical Phase I	75	73	75
Clinical Phase II	50	45	50
Clinical Phase III	70	...	73
Approval	90	...	81

Table B. Probability of success for drug approval.

willingness to exercise its flexibility. The option value places a price on the value of this flexibility, and the ENPV identifies how much the firm should be willing to pay to keep the project (or option) open.

Real options analysis is based on the mathematics of financial options, and has received widespread attention and acclaim since the early 1990s. Few companies have extensive experience with real options. However one notable author feels that real options will replace NPV as the central method for investment decisions in the future.<sup>1</sup>

There are five primary variables involved in the option value calculation for financial assets. The Black-Scholes pricing model estimates the value of a simple call option (C) based on the current stock price ( $S_0$ ), strike price (X), volatility ( $\sigma$ ), risk-free interest rate (r), and the time to expiration (T). The equation is:

$$C = S_0 N(d_1) - Xe^{-rT} N(d_2) \quad (\text{Eq3})$$

where

$$d_1 = \frac{(\ln \frac{S_0}{X}) + (r + \frac{\sigma^2}{2}) T}{\sigma \sqrt{T}}$$

$$d_2 = d_1 - \sigma \sqrt{T}$$

$N(d_x)$  is the cumulative standard normal distribution of the variable  $d_x$ .

The five variables of financial options have direct equivalents in real assets - Table A.<sup>3,5</sup> Note: of the five variables used in real options analysis, four are used to calculate NPV and are usually available to the analyst. The new variable that needs to be considered is the volatility of the project's future rate of return.

The value of simple options can be quickly calculated using the Black-Scholes model, but the math becomes very complex if the option becomes more complicated. Binomial lattices also can be used to determine the value of financial and real options, and is a preferred method for complex options. This technique is explained later.

Compound options are those options that are dependent on the value of other options.<sup>6</sup> Compound options can be sequential, and are sometimes called staging options. Many projects are funded in phases; good project management encourages this approach. If there is a phased investment, and succeeding investments are dependent on previous

investments, then a sequential compound (staging) option may exist.<sup>7</sup> Virtually all drug development projects are phased investments, and most are sequential compound options.<sup>8</sup>

## The Costs of Clinical Trials

In 2003, the average cost for testing and successfully launching a new drug was estimated at \$900 million.<sup>9</sup> While there are significant costs involved in launching a new product, much of the total cost is associated with clinical trials. The costs of a clinical trial include trial design, patient recruitment, clinician cost, product cost, monitoring, data analysis, close out and reporting results, coordination with regulatory authorities, and administrative costs.<sup>10</sup> Antibacterial trials are particularly expensive to run, and can cost \$50,000 per patient; one Phase III trial can cost half a billion dollars.<sup>11</sup> Clinical trial costs vary depending on the type of drug, the number of people involved in the trial, and the product claims that are trying to be proven. Increasingly, marketing claims are driving additional clinical trials in order to 'position' a product in the marketplace.<sup>12</sup>

## Case Study

The following hypothetical case study was published as an example of evaluating a drug development opportunity.<sup>13</sup> The case has been used in several business schools as an example of how to use decision trees to perform valuation studies.

A small pharmaceutical firm has developed a new chemical compound that they believe has a good chance of becoming a prescription drug. The chemical is called Davanrik, and has the potential to treat both depression and obesity. The small firm lacks the resources to complete the approval process, and so has approached a large pharmaceutical company with a proposal to license the chemical and complete the drug development process. At the time of the licensing offer, Davanrik was finishing pre-clinical development and was

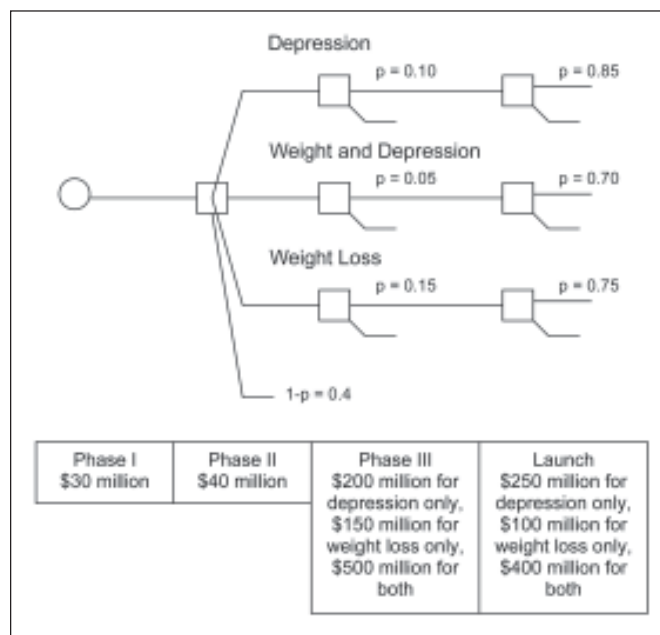


Figure 1. Davanrik decision tree.

getting ready to enter clinical testing.

The testing and approval process was expected to take seven years. If all went according to plan, Davanrik would have 10 years of exclusive marketing rights, beginning with the New Drug Application (NDA) approval. The typical probabilities of success for each clinical phase are known in the drug industry; these are shown in - *Table B*. One of the largest risks in the drug industry is the clinical development process. The value of a drug development project is determined in part by evaluating the probabilities of success at each stage of the clinical process.

During clinical testing, Davanrik would be given to 20 – 80 healthy people to determine human safety.<sup>16</sup> The testing was expected to cost \$30 million and take two years to complete with an estimated 60% chance of success.

During clinical testing, the chemical would be given to 100 – 300 people to determine the efficacy for treating depression and/or weight loss. The probability of success for the depression indication was estimated at 10%, the probability of success for the weight loss indication was estimated at 15%, and the probability of both indications being successful was estimated at a 5% probability. Phase II testing was expected to require two years to complete, and would cost \$40 million.

In Phase III clinical testing, Davanrik would be given to 1000 – 5000 people to determine safety and efficacy in a broad spectrum of the population. This testing was expected to take three years to complete and depended on successful results from Phase II. If the earlier testing demonstrated that the chemical was effective only for depression, then the Phase III trials would cost \$200 million and have an 85% chance of success. If Davanrik were found to be effective for weight loss only, then the trials would cost \$150 million and have a 75% chance for success. If Davanrik were found to be effective for both, then the cost of Phase III would be \$500 million with a 70% chance of success.

Davanrik has the potential of generating large profits. If the drug were approved only for depression, it would cost \$250 million to launch, with a present value of future cash flows of \$1.2 billion. If Davanrik were approved only for weight loss, it would cost \$100 million to launch with a present value of future cash flows of \$345 million. If the chemical were approved for both depression and weight loss, it would cost \$400 million to launch with a present value of future cash flows of \$2.25 billion. All costs have already been discounted to the present time. While the development costs are high and the chances of success are low, the potential payout is very high if success can be achieved. The question therefore becomes: Should Davanrik be licensed?

### The Decision Tree and Traditional Valuation

Figure 1 shows a decision tree for the Davanrik problem. The tree starts in year zero with the beginning of Phase I; this phase lasts two years and costs \$30 million. The probability of success is 60%. If Phase I is successful, then Phase II may begin. Phase II lasts two years and will cost \$40 million. The chance of success for Davanrik as a depression medication is 10%; the chance of success for weight loss is 15%; and the

Indication	Discounted Income	Discounted Cost	Net Present Value
Depression	58.14	42.75	\$15.39 million
Weight Loss	22.13	38.25	- \$16.12 million
Both	44.89	41.40	\$3.49 million

Table C. NPV results.

chance of success for both is 5%. This relatively low probability of success is in line with industry norms.<sup>10</sup> If any of these are successful, then Davanrik may enter Phase III testing. Each of the indications has its own cost and probability of success. If Phase III is successful, then the product may be launched, pending FDA approval.

We can analyze this information using traditional methods. The most commonly used valuation method is NPV. Using the potential income, potential costs, and the probability of each, a Net Present Value can be determined for each indication. First look at costs, beginning at time  $T = 7$  years. Normally, costs would need to be discounted back to time zero, but the costs have already been discounted. It is assumed that payments are made at the conclusion of each phase. Assuming Phase III is successful, we have two costs at  $T=7$ : the Phase III cost and the product launch cost. The Phase III clinical study will need to be paid for, but the product will be launched only if it is successful. For the depression indication, this includes \$250 million for the launch and \$200 million for the Phase III study. At year seven, the probability-adjusted costs are (*Figure 1*):

$$\text{Depression cost} = 200 + (.85)(250) = \$412.5 \text{ in Year zero dollars}$$

$$\text{Weight loss cost} = 150 + (.75)(100) = \$225$$

$$\text{Both cost} = 500 + (.70)(400) = \$780$$

Assume that the \$40 million cost of the Phase II clinical study is divided equally between the three possible indications. At year four, the probability-adjusted costs are:

$$\text{Depression cost} = 40/3 + (412.5)(0.1) = \$54.58$$

$$\text{Weight loss cost} = 40/3 + (225)(0.15) = \$47.08$$

$$\text{Both cost} = 40/3 + (780)(0.05) = \$52.33$$

At year two, the end of Phase I, the probability-adjusted costs are:

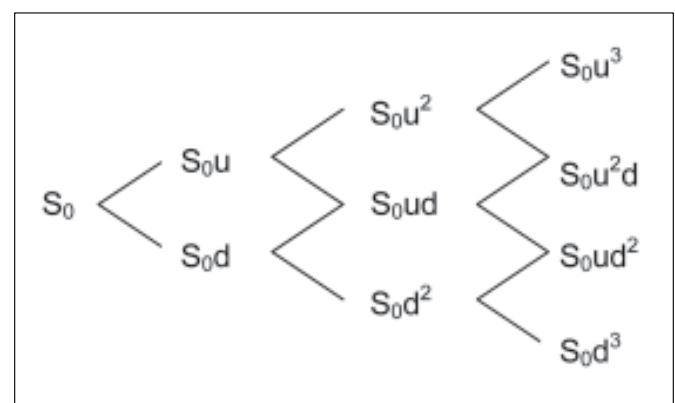


Figure 2. The Binomial lattice.

Indication	NPV	ENPV
Depression only	15.4	740.18
Weight loss only	-16.1	120.3
Both depression and weight loss	3.5	1367.8

Table E. NPV and options analysis results.

$$\begin{aligned} \text{Depression cost} &= 30/3 + (54.58)(0.6) = \$42.75 \text{ million} \\ \text{Weight loss cost} &= 30/3 + (47.08)(0.6) = \$38.25 \text{ million} \\ \text{Both cost} &= 30/3 + (52.33)(0.6) = \$41.40 \text{ million} \end{aligned}$$

Because all of these costs were already discounted to year zero, these are also the probability-weighted costs for the three options at year zero.

The income also can be determined using decision trees. The income streams have already been discounted so we do not need to adjust for time, only probability. The income stream will occur only if all tests are successful so the probability is based on success of all clinical trials. A royalty of 5% is assumed, decreasing all future income to a factor of 0.95.

$$\begin{aligned} \text{Depression income} &= (1200)(0.6)(0.10)(0.85)(0.95) \\ &= \$58.14 \text{ million} \\ \text{Weight loss income} &= (345)(0.6)(0.15)(0.75)(0.95) \\ &= \$22.13 \text{ million} \\ \text{Both} &= (2250)(0.6)(0.05)(0.70)(0.95) \\ &= \$44.89 \text{ million} \end{aligned}$$

We can determine the NPV by subtracting the costs from the income - *Table C*.

Strictly speaking, the NPV technique indicates that the project should be undertaken for depression and for the dual indication, but not weight loss. If the weight loss indication were not pursued, the costs that were assumed by the weight loss indication would need to be shifted to the other options, increasing their costs. At year four, the probability adjusted costs then become:

	Depression	Weight Loss	Both
PV of the future cash flows	1200	345	2250
Royalty paid (5%)	60	17.25	112.5
Effective PV of future cash flows, S	1140	327.75	2137.5
Launch cost, X4	250	100	400
Phase 3 cost, X3	200	150	500
Phase 2 cost, X2	13.33	13.33	13.33
Phase 1 cost, X1	10.0	10.0	10.0
Time for the launch (years)	7	7	7
Time for Phase 3 (years)	7	7	7
Time for Phase 2 (years)	4	4	4
Time for Phase 1	2	2	2
r (risk-free interest rate)	5%	5%	5%
Estimated volatility	40%	40%	40%

Table D. Davanrik variables.

$$\begin{aligned} \text{Depression cost} &= 40/2 + (412.5)(0.1) = \$61.25 \\ \text{Both cost} &= 40/2 + (780)(0.05) = \$59.00 \end{aligned}$$

At year two, the end of Phase I, the probability-adjusted costs are:

$$\begin{aligned} \text{Depression cost} &= 30/2 + (61.25)(0.6) = \$51.75 \\ \text{Both cost} &= 30/2 + (59.00)(0.6) = \$50.40 \end{aligned}$$

The Net Present Value then becomes:

$$\begin{aligned} \text{Depression NPV} &= 58.14 - 51.75 = \$6.39 \\ \text{Both cost} &= 44.89 - 50.40 = -\$5.51 \end{aligned}$$

The NPV for "Both" is not viable, making it so that the depression indication must assume all Phase I and Phase II costs. When the NPV for the depression indication alone is calculated in a similar way, the result is -\$20.61. The recommendation would be that the Davanrik licensing agreement should not be pursued.

Even the most generous of organizations would have concerns over funding this project. The payback method, still used by many organizations, shows that the project will not pay its costs until late in the project's life. The Internal Rate of Return (IRR) analysis shows that the project might return the weighted average cost of capital under the best of conditions, but not much more. Under any traditional test method, if the weight loss indication is not pursued, the other projects cannot afford to cover the fixed costs of the early clinical testing. This is a scenario where NPV is close to zero, and management spends significant time gathering information in order to make the best possible decision. An advocate of this project will need to produce a different rationale to justify moving forward. Options analysis could help such an advocate.

## The Davanrik Project as a Sequential Compound Option

The value of the real option can be calculated with the binomial options approach, using a lattice to demonstrate alternative possibilities over time.<sup>17</sup> The starting point is the present value of the future cash flows ( $S_0$ ). Over time T, two conditions can result at each decision point: one positive up outcome and one negative down outcome (hence the term binomial). Over several time steps, we can create a lattice as shown in - *Figure 2*.

The option valuations require a risk-free rate of return. For the binomial lattices to work correctly, costs will be compounded at the risk-free rate so that standard time value of money equations can be used for discounting. In effect, the costs and incomes will be compounded at 5% so that they can later be discounted at the same 5%.

In order to calculate the option value using binomial lattices, the variables need to be identified. For the Depression indication:

$$\begin{aligned} \text{Present value of future cash flows, PV} &= 1200 \\ \text{Royalty paid (5\%)} &= (1200)(0.05) = 60 \\ \text{Effective PV of the future cash flows, S} &= 1200 - 60 = 1140 \\ \text{Cost of product launch, X4} &= 250 \\ \text{Cost of Phase III, X3} &= 200 \end{aligned}$$

Time steps:	0	1	2	3	4	5	6	7
								18746.90
						8423.52	12566.42	8423.52
				5646.46	3784.93	5646.46	3784.93	5646.46
			3784.93	2537.12	3784.93	2537.12	3784.93	2537.12
		1700.68	2537.12	1700.68	2537.12	1700.68	2537.12	1700.68
	1140.00	1140.00	1140.00	1140.00	1140.00	1140.00	1140.00	1140.00
	784.16	784.16	784.16	784.16	784.16	784.16	784.16	784.16
		512.24	512.24	512.24	512.24	512.24	512.24	512.24
			343.38	343.38	343.38	343.38	343.38	343.38
				230.16	230.16	230.16	230.16	230.16
					154.28	154.28	154.28	154.28
						103.42	103.42	103.42
								69.32

Figure 3. Depression underlying lattice.

- Cost of Phase II,  $X2 = 40/3 = 13.33$
- Cost of Phase I,  $X1 = 30/3 = 10.0$
- Time for the launch and for Phase III = 7 years
- Time for Phase II = 4 years
- Time for Phase I = 2 years
- Risk-free interest rate  $r$  is assumed to be 5%
- Volatility must be estimated

There are several ways to estimate the volatility of projects, but these methods will not be investigated in this article.<sup>18</sup> Merck generally begins an analysis based on a volatility of 40%;<sup>19</sup> and we will use the same.

We need to determine a few variables that are used to solve the binomial lattice. The up step ( $u$ ) is defined as:

$$u = e^{\sigma\sqrt{\delta T}} \quad (\text{Eq4})$$

where  $\delta T$  is the change ( $\delta$ ) in time ( $T$ ) for the step.

The binomial lattice is constructed so that each time-step is equal to one year, so  $\delta T = 1$ .

$$u = e^{0.4\sqrt{1}} = 1.492 \quad (\text{Eq5})$$

The down step ( $d$ ) is defined as  $1/u$ ,

$$d = 1/u = 0.670 \quad (\text{Eq6})$$

Instead of discounting our cash flows at a risk-adjusted rate, as is often done in discounted cash flow analysis, we can determine a risk-neutral probability and then discount our cash flows at a risk-free rate. This is the standard technique used for building binomial lattices as they are used in valuing options.<sup>20</sup> The risk-neutral probability  $p$  is

$$p = \frac{e^{r\delta T} - d}{u - d} = \frac{e^{0.05*1} - 0.670}{1.492 - 0.670} = 0.4637 \quad (\text{Eq7})$$

The variables for the other indications can be calculated if they are not given. A summary of the input variables is shown in - *Table D*.

The option value for the depression indication may be calculated using the technique for sequential compound options.<sup>20</sup> In this case, we have four sequential options. Phase I clinical testing occurs first, and future work may not continue without success in Phase I. Therefore, Phase II is dependent on the successful completion of Phase I. Similarly, Phase III is dependent on Phase II, and product launch is

Time steps:	0	1	2	3	4	5	6	7
								18382.13
						8102.52	12228.96	8102.52
					5341.11	5341.11	5306.99	8068.76
				3494.47	2231.77	3494.47	2199.65	3430.17
			2261.22	1410.99	2261.22	1379.67	2199.65	1345.91
		1442.44	872.34	1410.99	836.16	1379.67	802.54	1345.91
	905.08	526.96	872.34	489.95	836.16	446.13	802.54	409.40
			276.69	489.95	237.43	446.13	180.59	409.40
				122.65	237.43	79.66	180.59	0.00
					35.14	79.66	0.00	0.00
						0.00	0.00	0.00
							0.00	0.00
								0.00

Figure 4. Depression equity lattice at Launch.

dependent on Phase III (as well as FDA approval). Due to the complex nature of this sequence, the binomial lattice method is the simplest method for the calculation of the option value. The calculation consists of five lattices, each related to the previous one.<sup>20</sup> Microsoft Excel is used to speed the calculations. The first lattice is the underlying lattice, starting with the value of  $S$  on the left (\$1140 million). This is shown in Figure 3 with time steps of one year. Each step is calculated with an up-step being

$$u = e^{\sigma\sqrt{\delta T}} = e^{0.4\sqrt{1}} = 1.492$$

The up-step is 1.492 times the previous value, and a down-step is  $1/u$ , or 0.670 times the previous value.

The next lattice is the equity lattice for the execution of the project - *Figure 4*. For this lattice, the cost incurred for the launch of the project is subtracted from the value at year seven (shown in the right hand column - *Figure 3*). This forms the basis for the new right-hand column - *Figure 4*. The successive columns to the left are then discounted by the equation

$$V_{t-1} = [(p)(V^+) + (1-p)(V)]e^{-r\delta T} \quad (\text{Eq7})$$

where

$V_{t-1}$  is the value in the next column to the left

$p$  is the risk-neutral probability

$V^+$  is the upper value (the up-step)

$V$  is the lower value (the down-step)

$r$  is the risk-free interest rate

$\delta T$  is the length of the time step

Time steps:	0	1	2	3	4	5	6	7
								18108.32
						7845.71	11958.98	7784.94
					5080.54	3207.12	5039.02	3146.35
				3246.62	1971.20	3207.12	1929.68	3146.35
			2024.20	1182.36	1971.20	1122.87	1929.68	1062.10
		1238.61	677.71	1182.36	613.28	1122.87	532.56	1062.10
		379.95	677.71	327.79	613.28	263.18	532.56	125.58
			158.80	327.79	112.27	263.18	55.40	125.58
				49.52	112.27	24.44	55.40	0.00
					0.00	24.44	0.00	0.00
						0.00	0.00	0.00
							0.00	0.00
								0.00

Figure 5. Depression equity lattice at Phase 1.

# Options Analysis

The entire lattice is completed from right to left. Given the values in year seven, the top number in the lattice for year six is  $V_{t-1} = [(0.4637)(18392.13) + (1-0.4637)(8068.76)]e^{-(0.05)(1)} = 12228.96$ .

The next lattice is the equity lattice for Phase III of the project. This lattice is not shown by itself, but can be seen in the top right corner of the five-lattice diagram of - Figure 6. For this lattice, the cost incurred for the third clinical phase is subtracted from the value at year seven in the previous

lattice, creating the new right-hand column. The successive columns to the left are discounted using the same risk-neutral probability.

The next lattice is the equity lattice for Phase II of the project. Again, this lattice is not shown by itself but can be seen in Figure 6. The cost incurred for the second clinical phase, which occurs in year four, is subtracted from the value at year four in the previous lattice. This lattice will have the same values as the previous lattice for years five, six, and

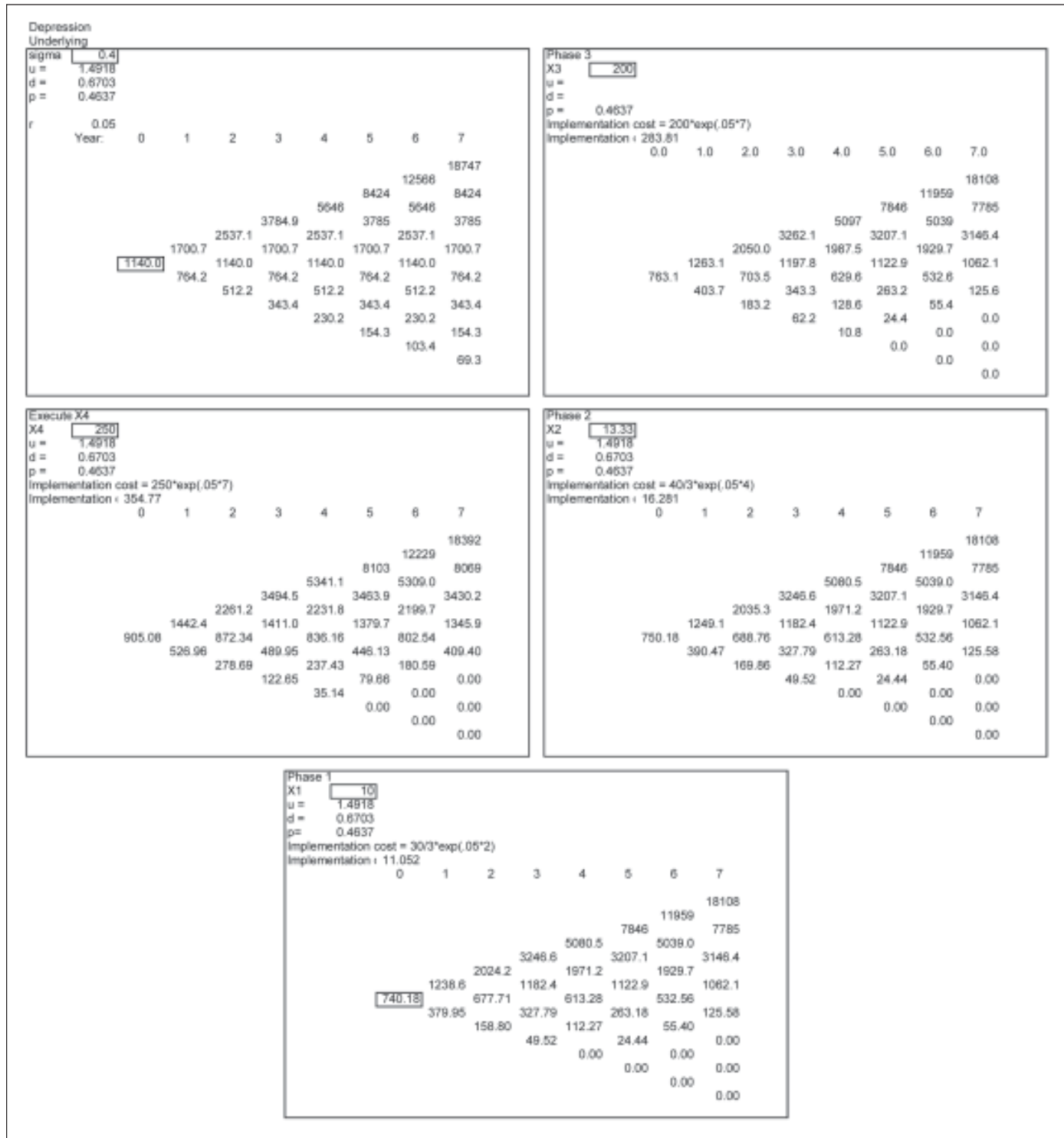


Figure 6. Five-lattice binomial calculation, depression indication.

seven. A new year-four column is created and the columns to the left are again discounted as before.

The final lattice is the equity lattice for Phase I of the project - *Figure 5*. For this lattice, the cost incurred for one-third of the first clinical phase, which occurs in year two, is subtracted from the value at year two in the previous lattice. This lattice will have the same values as the previous lattice for years three through seven. A new year-two column is created, and the columns to the left are calculated as before. The far left hand column of this last lattice represents the value of the option in year zero, and provides the value of the option. This is also the ENPV of the project. The ENPV for the Depression indication is \$740.18 million.

The value for this option is clearly higher than the NPV calculation of \$15.39 million. This is due to several factors. First, the option never achieves a value below zero. If conditions indicate that the value would be negative, then the option (or project) would not be executed and the value is simply zero. This represents the value of management's flexibility to not fund a money-losing project. Second, this is a high-risk project with a very large potential payout. Whereas NPV decreases the value of the project when risk is present, options analysis increases the value when risk is present. The chances of having a positive decision are enhanced with options analysis.

The primary question at this point is whether it is worthwhile to fund the beginning of this project. For the Depression indication, the project needs to justify the expenditure of \$10 million for its fair share of Phase I clinical testing. Managers are not being asked to fund the entire project, only the first phase. Based on the option analysis, this method says that project expenditures of up to \$740.18 million are justified.

Similarly, the option values for the other indications can be calculated. A summary of the results is shown in - *Table E*. For all indications, the ENPV is substantially higher than the previously calculated NPV.

The ENPV gives a clear signal that the project should be undertaken. Real Options Analysis was able to improve the decision where NPV analysis was not clear. The project should be continued if the Phase I clinical trials are successful. If they are not successful, then the project should be abandoned. The project should again be evaluated before Phase II money is committed. The complete five-lattice binomial calculation is shown in - *Figure 6*.

### Implications for the Pharmaceutical Engineer

The valuation of a project is an aspect of project management that can be crucial to the success of a project. Valuation is discussed extensively in the academic literature and in the popular business press. The issue is relevant to anyone who is attempting to justify a project. Valuation is also relevant to business accounting and finance, and is an important part of tax law. Discounted cash flow analysis is widely used in the pharmaceutical industry, and engineers need to be aware of the problems that these methods present. Discounted cash flow undervalues many projects, whereas the use of real options helps to determine a more accurate project value.

A key advantage in the use of the staging option is that it assumes that future costs will be spent only if it is in the best interest of the firm to do so. A future phase will be undertaken only if the previous phase is successful. This is a much different assumption than NPV, where future costs are adjusted only by their estimated probability of occurrence.

Options analysis has been criticized for being a "black box." Many managers do not understand the methods and do not understand how a given option value is calculated. The binomial lattice approach is a flexible technique that is based on simple mathematics. The method is easy to learn and can be understood by a wide range of interested parties. Advanced mathematics such as calculus is not needed when using the binomial lattice approach. This method helps alleviate the "black box" mentality that has hindered the application of options analysis in the past.

Real option values are determined based on a set of forecasts, including future cash flows and future costs. It is therefore necessary to realize that option values are estimates, and are only as accurate as the input variables. When necessary, sensitivity analysis can be applied to option analysis.

The staging option is one of several related real options tools available to the pharmaceutical engineer. Projects are sometimes delayed until additional information can be obtained. In this case, a deferral option may be a useful analysis tool. Projects are abandoned for a variety of reasons, in which case an abandonment option could prove useful. Projects can be expanded or contracted depending on market success, and the expansion option or the contraction option can be used to better define the worth of such projects. While these options are beyond the scope of this article, they are analysis tools that can aid in project valuation.

### Conclusions

Staging options can be used to provide a more accurate project valuation when NPV is not decisive. By approaching projects with a staged investment strategy, we limit the investment and the risk at the early stages. This also provides time for better understanding of the future cash flows and costs, allowing managers to make better decisions as uncertainty is resolved and project outcomes are more clearly defined. This approach can be used in a variety of industries, and is very applicable to medium and large projects. It is especially useful in the pharmaceutical industry where drug development is required to be a staged investment.

Drug development can often be viewed as a sequential compound option. As an option, funding of a development project first hinges on the decision to fund the first round of testing. The entire project does not need to be funded at one time. Management has the option of either funding or abandoning the project at a later date, and this option has value. Early stages require a relatively small initial investment compared to the potentially large future funding requirements so options analysis may alter the decision of whether to fund the project. Most of the information needed to perform the options analysis is the same as would be used to determine a project's NPV with the exception of volatility. The

volatility of the project's future returns must often be estimated, and this volatility can be difficult to determine. Furthermore, calculation of the expanded NPV is more complex than determining the traditional NPV, but the binomial lattice approach provides a value without the use of complex mathematics. The calculation method using the binomial lattice has been demonstrated, and shown to be a relatively straight-forward method for calculating option value.

The staging option is an important approach for all kinds of projects since much of the project work is performed using staged funding. The demonstrated case study clearly shows how the final decision can change when viewed from an options perspective.

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