CASE STUDY: PHARMACEUTICAL AND BIOTECH DEAL STRUCTURING

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Smaller companies in the biotechnology industry rely heavily on alliances with pharmaceutical and larger companies to finance their R&D expenditures. Pharmaceutical and larger organizations in turn depend on these alliances to supplement their internal R&D programs. In order for smaller organizations to realize the cash flows associated with these alliances, they must have a competent and experienced business development component to negotiate and structure these crucial deals. In fact, the importance of these business collaborations to the survival of most young companies is so great that deal-making experience, polished business-development skills, and a substantial network of contacts are all frequent assets of the most successful executives of start-up and early-stage biotechnology companies.

Although deal-making opportunities for biotech companies are abundant because of the pharmaceutical industry's need to keep a healthy pipeline of new products in development, in recent years deal-making opportunities have lessened. Intuitively, then, firms have to be much more careful in the way they structure and value the deals in which they do get the opportunity to participate. However, despite this importance, a large number of executives prefer to go with comparable business deal structures for these collaborations in the hope of maximizing shareholder value for their firms, or by developing deal terms using their own intuition rather than developing a quantitative methodology for deal valuation and optimization to supplement their negotiation skills and strategies. For companies doing only one deal or less a year, perhaps the risk might be lower by structuring a collaboration based on comparable deal structures; at least they will get as much as the average company, or will they?

As described in this case study, *Monte Carlo simulation*, *stochastic optimization*, and *real options* are ideal tools for valuing and optimizing the

financial terms of collaborative biomedical business deals focused on the development of human therapeutics. A large amount of data associated with clinical trial stage lengths and completion probabilities are publicly available. By quantitatively valuing and structuring deals, companies of all sizes can gain maximum shareholder value at all stages of development, and, most importantly, future cash flows can be defined based on expected cash-flow needs and risk preference.

Deal Types

Most deals between two biotechnology companies or a biotechnology company and pharmaceutical company are strategic alliances where a cooperative agreement is made between two organizations to work together in defined ways with the goal of successfully developing or commercializing products. As the following list describes, there are several different types of strategic alliances:

- *Product Licensing.* A highly flexible and widely applicable arrangement where one party wishes to access the technology of another organization with no other close cooperation. This type of alliance carries very low risk and these types of agreements are made at nearly every stage of pharmaceutical development.
- *Product Acquisition.* A company purchases an existing product license from another company and thus obtains the right to market a fully or partially developed product.
- *Product Fostering.* A short-term exclusive license for a technology or product in a specific market that will typically include hand-back provisions.
- *Comarketing.* Two companies market the same product under different trade names.
- *Copromotion.* Two parties promote the same product under the same brand name.
- *Minority Investment Alliance.* One company buys stock in another as part of a mutually desired strategic relationship.

The historical agreement valued and optimized in this case study is an example of a product-licensing deal.

Financial Terms

Each business deal is decidedly unique, which explains why no "generic" financial model is sufficient to value and optimize every opportunity and collaboration. A biomedical collaborative agreement is the culmination of the

combined goals, desires, requirements, and pressures from both sides of the bargaining table, possibly biased in favor of one party by exceptional negotiating skills, good preparation, more thorough due diligence, and accurate assumptions, and less of a need for immediate cash.

The financial terms agreed on for licensing or acquiring a new product or technology depend on a variety of factors, most of which impact the value of the deal. These include but are not limited to:

- Strength of the intellectual property position.
- Exclusivity of the rights agreed on.
- Territorial exclusivity granted.
- Uniqueness of the technology transferred.
- Competitive position of the company.
- Stage of technology developed.
- Risk of the project being licensed or sold.

Although every deal is different, most include: (1) licensing and R&D fees; (2) milestone payments; (3) product royalty payments; and (4) equity investments.

Primary Financial Models

All calculations described in this case study are based on discounted cashflow (DCF) principals using risk-adjusted discount rates. Here, assets under uncertainty are valued using the following basic financial equation:

$$NPV = \sum_{i=0}^{n} \frac{E(CF_t)}{(1 + r_t + \pi_t)^t}$$

where NPV is the net present value, $E(CF_t)$ is the expected value of the cash flow at time t, r_t is the risk-free rate, and π_t is the risk premium appropriate for the risk of CF_t.

All subcomponents of models described here use different discount rates if they are subject to different risks. In the case of biomedical collaborative agreements, all major subcomponents (licensing fees, R&D costs and funding, clinical costs, milestone payments, and royalties) are frequently subject to many different distinct risks, and thus are all assigned their own discount rates based on a combination of factors, with the subject company's weighted average cost of capital (WACC) used as the base value. To incorporate the uncertain and dynamic nature of these risk assumptions into the model, all of these discount rates are themselves Monte Carlo variables. This discounting supplementation is critical to valuing the deal accurately, and most important for later stochastic optimization.

Historical Deal Background and Negotiated Deal Structure

The deal valued and optimized in this case study was a preclinical, exclusive product-licensing agreement between a small biotechnology company and a larger organization. The biopharmaceutical being valued had one major therapeutic indication, with an estimated market size of $1 billion at the date the deal was signed. The licensee negotiated the right to sublicense. The deal had a variety of funding provisions, with a summary of the financial terms presented in Table 7.1. The licensor estimated they were approximately 2 years away from filing an investigational new drug (IND) application that would initiate clinical trials in humans. For the purposes of the deal valuation and optimization described here, it is assumed that no information asymmetries exist between the companies forming the collaboration (i.e., both groups feel there is an equally strong likelihood their candidate biopharmaceutical will be a commercial success).

Licensing fees for the historical deal consisted of an up-front fee followed by licensing maintenance fees including multipliers (Table 7.1). Licensing maintenance fees will terminate on any one of the following events: (1) first IND filing by licensor; (2) tenth anniversary of the effective date; and (3) termination of the agreement. Milestone values for the historical deal numbered only three, with a $500,000 payment awarded on IND filing, a $1,500,000 payment on new drug application (NDA) filing, and a $4,000,000 payment on NDA approval (Table 7.1). The negotiated royalties for the historical deal were a flat 2.0 percent of net sales.

As described later in this case, two additional deal scenarios were constructed and stochastically optimized from the historical structure: a higher-value, lower-risk (HVLR) scenario and a higher-value, higher-risk (HVHR) scenario (Table 7.1).

Major Assumptions Figure 7.1 shows a time line for all three deal scenarios evaluated. Also shown are the milestone schedules for all three scenarios, along with major assumption data. The total time frame for all deal calculations was 307.9 months, where the candidate pharmaceutical gains a 20 percent maximum market share of a 1 billion dollar market, with a 20 percent standard deviation during the projected 15-year sales period of the pharmaceutical. The market is assumed to grow 1.0 percent annually starting at the effective date of the agreement and throughout the valuation period. The manufacturing and marketing costs of the potential pharmaceutical were estimated to be 58 percent, an important assumption considering that royalties are paid on net sales, not gross sales. The total market size, market growth rate, maximum market share, and manufacturing and marketing offset are all Monte Carlo variables following lognormal distributions where

TABLE 7.1 Historical Financial Terms Granted to the Licensor of the Signed Biomedical Collaborative Deal Valued and Optimized in This Case Study

	Deal Scenario			
Component	Historical	Higher-Value, Lower-Risk	Higher-Value, Higher-Risk	Timing
Licensing Fees	$100,000	$125,000	$ 85,000	30 days from effective date
Licensing Maintenance Fees	$100,000	$125,000	$ 75,000	First anniversary
	200,000	250,000	150,000	Second anniversary
	300,000	375,000	225,000	Third anniversary
	400,000	500,000	300,000	Fourth anniversary
	500,000	500,000	300,000	Fifth anniversary
R&D Funding	$250,000	$275,000	$165,000	Per year
Milestone Payments	$500,000	$660,000	$910,000	First IND filing in United States or European equivalent
		895,000		Successful conclusion of Phase I clinical trials in the United States or European equivalent
		1,095,000	1,400,000	Successful conclusion of Phase II clinical trials in the United States or European equivalent
	1,500,000	1,375,000	1,650,000	First PLA[a] (or NDA[b]) filing or European equivalent
	4,000,000	1,675,000	1,890,000	NDA approval in the United States or European equivalent
Royalties	2.0% Net Sales	0.5% Net Sales	5.5% Net Sales	

[a]Product license application.

[b]New drug application.

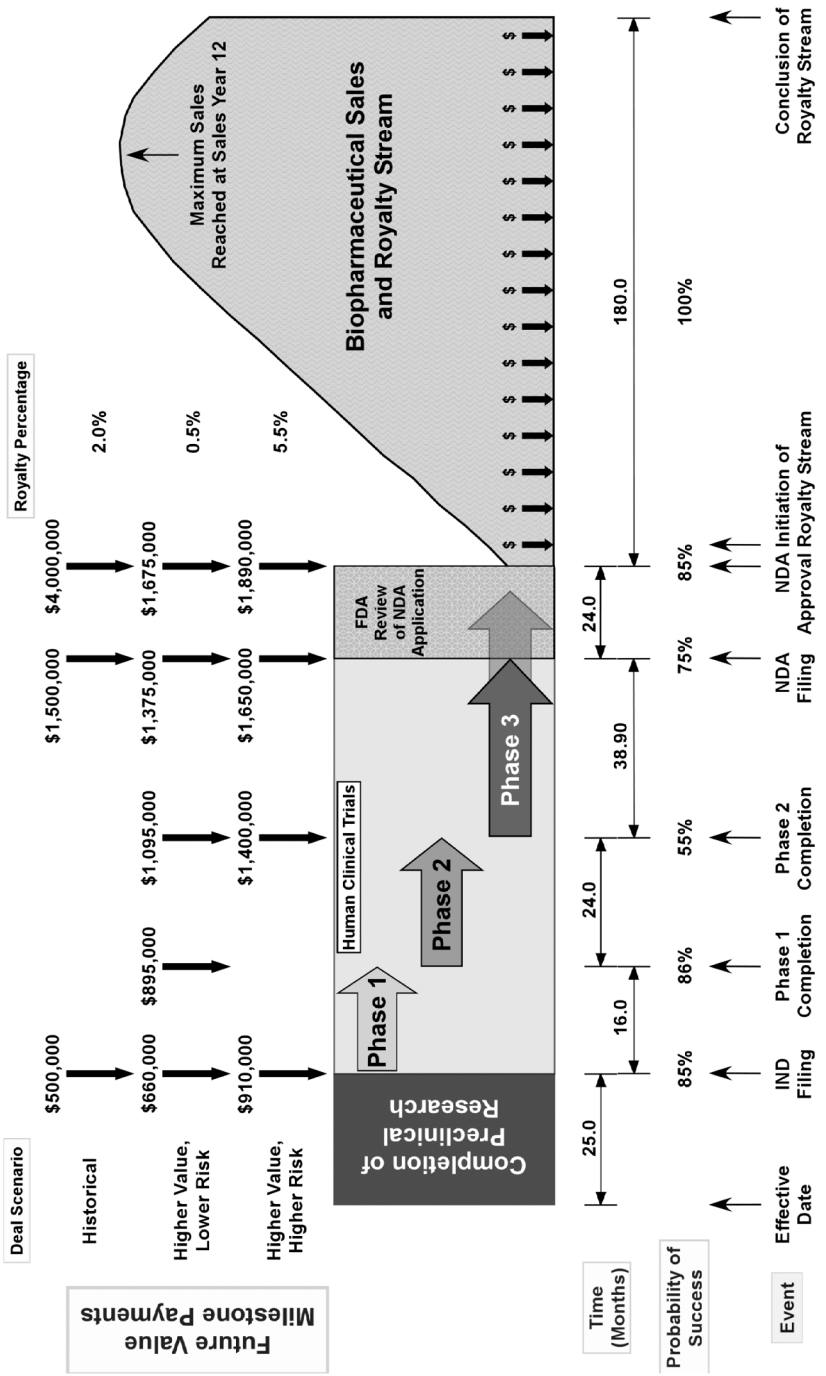

FIGURE 7.1 Time line for the biomedical licensing deal. Milestone and royalty values for all deal scenarios evaluated are shown. R&D, licensing, and licensing maintenance fees are not shown.

extreme values are unlikely. Assumptions regarding clinical trial length, completion probabilities, and major variables in the valuation model are also shown in Figure 7.1. All of these values are Monte Carlo assumptions. Throughout this case study, deal values were based on royalties from 15 years of net sales. Royalties were paid on a quarterly basis, not at the end of each sales year. Total R&D costs for the licensor were $200,000 annually, again estimated with a Monte Carlo assumption.

Inflation during the period was assumed to be 1.95 percent annually and average annual pharmaceutical price increases (APPIs) were assumed to be 5.8 percent. Thus, milestones were deflated in value, and royalties inflated by APPI less inflation. For the deal valuation described here, the licensor was assumed to be unprofitable preceding and during the clinical trial process and milestone payments were not subject to taxes. However, royalties from the licensee paid to the licensor were taxed at a 33.0 percent rate.

Deal Valuations

Historical Deal Valuation Figure 7.2 illustrates the Monte Carlo summary of the historical deal, while Figure 7.3 shows a comparative illustration of each major component of the historical scenario. Mean deal present value was $1,432,128 with a standard deviation of $134,449 (Figure 7.2). The distri-

Certainty is 50.00% from $1,338,078 to $1,515,976.

Summary

Certainty level is 50.00%.
Certainty range is from $1,338,115 to $1,516,020.
Display range is from $1,091,067 to $1,772,886.
Entire range is from $994,954 to $2,037,413.
After 10,000 trials, the standard error of the mean is $1,344.

Statistics

Trials	10,000
Mean	$1,432,128
Median	$1,422,229
Standard Deviation	$134,449
Variance	$18,076,644,871
Skewness	0.46
Kurtosis	3.47
Coefficient of Variability	9.38%
Range Minimum	$994,954
Range Maximum	$2,037,413
Range Width	$1,042,459
Mean Standard Error	$1,344

FIGURE 7.2 Historical deal scenario Monte Carlo summary.

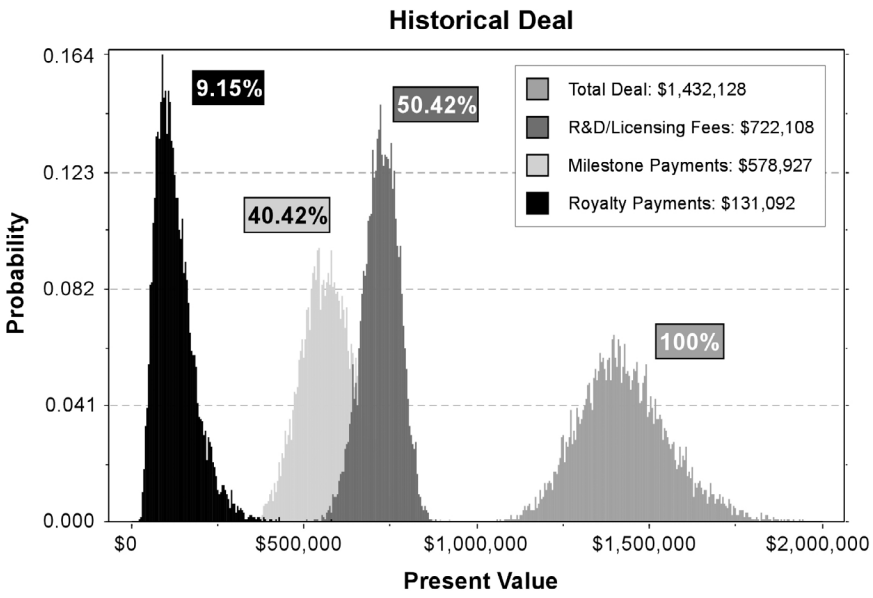

FIGURE 7.3 A comparative illustration I.
This is an illustration of the Monte Carlo distributions of the cash-flow present value of the historical deal scenario, along with the distributions of the deal's individual components. Each component has a clearly definable distribution that differs considerably from other deal components, both in value and risk characteristics. The percentage of each component to total deal present value is also shown.

bution describing the mean was relatively symmetric with a skewness of 0.46. The kurtosis of the distribution, the "peakedness," was 3.47 (excess kurtosis of 0.47), limiting the deal range from $994,954 to $2,037,413. The coefficient of variation (CV), the primary measure of risk for the deal, was low at 9.38 percent. R&D/licensing contributed the most to total deal value with a mean present value of $722,108, while royalties contributed the least with a mean value of $131,092 (Figure 7.3). Milestones in the historical scenario also contributed greatly to the historical deal value with a mean present value of $578,927.

The riskiness of the cash flows varied greatly among individual historical deal components. R&D/licensing cash flows varied the least and had by far the lowest risk with a CV of only 7.48 percent and, proportional to the distribution's mean, had the smallest range among any deal component (data not shown). The present value of milestone cash flows was much more volatile, with a CV of 14.58 percent. Here the range was greater ($315,103 to $1,004,563) with a symmetric distribution having a skewness of only 0.40 (data not shown).

Royalty present value was by far the most volatile with a CV of 45.71 percent (data not shown). The kurtosis of royalty present value was large (5.98; data not shown), illustrating the proportionally wide distribution to the small royalty mean ($131,093; Figure 7.3). These data should not be surprising as the royalty cash flows are subject to variability of nearly all Monte Carlo assumptions in the model and are thus highly volatile.

Monte Carlo Assumption and Decision Variable Sensitivities Figure 7.4 shows a tornado chart of historical deal assumptions and decision variables. The probability of IND filing had the largest influence on variation of total deal present value, as all milestones and royalties are dependent on this variable. Interestingly, next came the annual research cost for each full-time equivalent (FTE) for the licensor performing the remaining preclinical work in preparation for an IND filing, followed by the negotiated funding amount of each FTE (Figure 7.4). Thus, an area for the licensor to create shareholder value is to overestimate R&D costs in negotiating the financial terms for the deal, considering R&D/licensing funding contributed 50.42 percent of total deal present value (Figure 7.3). Variables impacting royalty cash flows, such as the royalty discount rate and manufacturing and marketing offset percentages, were more important than the negotiated milestone amounts, although the milestone discount rate was 10th in contribution to variance to the historical deal (Figure 7.4).

Higher-Value, Lower-Risk Deal Valuation

Changes in Key Assumptions and Parameters Differing from the Historical, Signed Deal The financial structure for the HVLR deal scenario was considerably different from the historical deal (Table 7.1). Indeed, R&D and licensing funding were significantly increased and the milestone schedule was reorganized with five payments instead of the three in the historical deal. In the HVLR scenario, the value of each individual milestone was stochastically optimized using individual restrictions for each payment. While the future value of the milestone payments was actually $300,000 less than the historical deal (Table 7.1), the present value as determined by Monte Carlo analysis was 93.6 percent higher. In devising this scenario, to compensate the licensee for increased R&D/licensing fees and milestone restructuring, the royalty value in the HVLR scenario was reduced to only a 0.5 percent flat rate (Table 7.1).

Deal Valuation, Statistics, and Sensitivities Figure 7.5 shows the Monte Carlo summary of the HVLR scenario, and Figure 7.6 shows an illustration of present value of the HVLR deal and its three components. The Monte Carlo mean deal value for this scenario was $2,092,617, an increase of 46.1 percent over

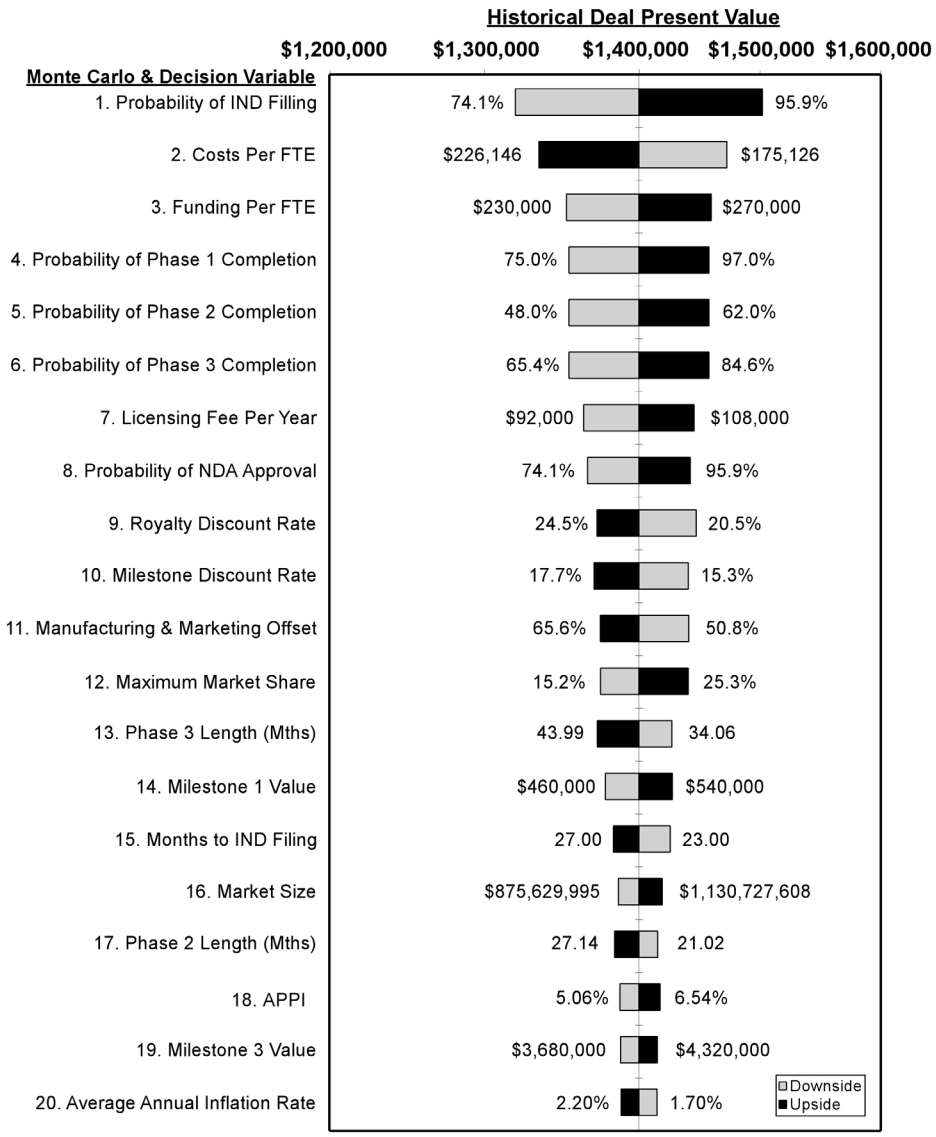

FIGURE 7.4 Historical deal Monte Carlo and decision variable tornado chart.

the historical deal, while total risk was reduced by 16.3 percent as measured by changes in the CV of cash-flow present value (Figures 7.2 and 7.5). This gain in total deal value was achieved by a 93.6 percent increase in the present value of milestone payments (Figures 7.3 and 7.6) along with a 9.6

Certainty is 50.00% from $1,980,294 to $2,200,228.

Summary

Certainty level is 50.00%.
Certainty range is from $1,980,218 to $2,199,958.
Display range is from $1,663,093 to $2,523,897.
Entire range is from $1,475,621 to $2,777,048.
After 10,000 trials, the standard error of the mean is $1,643.

Statistics

Trials	10,000
Mean	$2,092,617
Median	$2,087,697
Standard Deviation	$164,274
Variance	$26,986,218,809
Skewness	0.18
Kurtosis	3.06
Coefficient of Variability	7.85%
Range Minimum	$1,475,620
Range Maximum	$2,777,047
Range Width	$1,301,427
Mean Standard Error	$1,642

FIGURE 7.5 Higher-value, lower-risk deal scenario Monte Carlo.

percent reduction in milestone risk (data not shown). The present value of R&D/licensing funding also increased (30.1 percent) while there is a 22.5 percent reduction in risk. These gains came at the cost of royalty income being reduced by 75.1 percent (Figures 7.3 and 7.6).

The royalty component was so small and the mean so tightly concentrated that the other distributions were comparatively distorted (Panel A, Figure 7.6). If the royalty component is removed, the total deal, milestone, and R&D/licensing distributions are more clearly presented (Panel B, Figure 7.6). The milestone percentage of the total HVLR scenario was much higher than the milestone component of the historical deal, while the R&D/licensing fees of the HVLR structure were less than the historical structure (Figures 7.3 and 7.7).

Cumulatively, the HVLR scenario had a 16.9 percent reduction in risk in comparison to the historical deal (Figures 7.2 and 7.5), where the R&D/licensing and milestone cash flows of HVLR structure were considerably less risky than the historical scenario (data not shown). However, not surprisingly, the risk for the royalty cash flows of the HVLR structure remained nearly identical to that of the historical deal's royalties (data not shown).

Monte Carlo Assumption and Decision Variable Sensitivities The tornado chart for the HVLR deal is presented in Figure 7.8. As with the historical deal, the

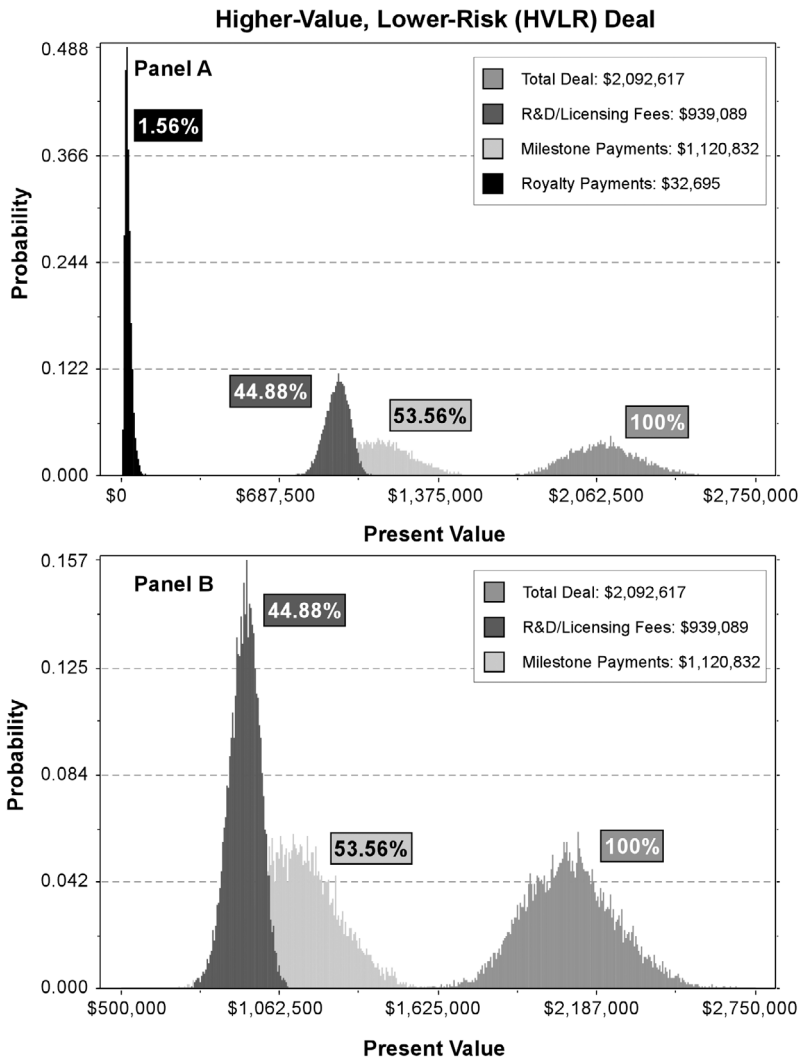

FIGURE 7.6 A comparative illustration II.
The figures illustrate the Monte Carlo distributions for cash-flow present value of the HVLR deal scenario along with the distributions of the deal's individual components. Because the royalty cash flows greatly distort the other distributions (Panel A), removing the royalties from the overlay chart allows the other distributions to be more clearly presented (Panel B). The data in Panel B are comparable to a similar representation of the historical deal (Figure 7.3). Here, proportionally, milestones contributed the most to deal value (53.56 percent), followed by R&D/licensing (44.88 percent), while royalties contributed very little (1.56 percent; Panel A).

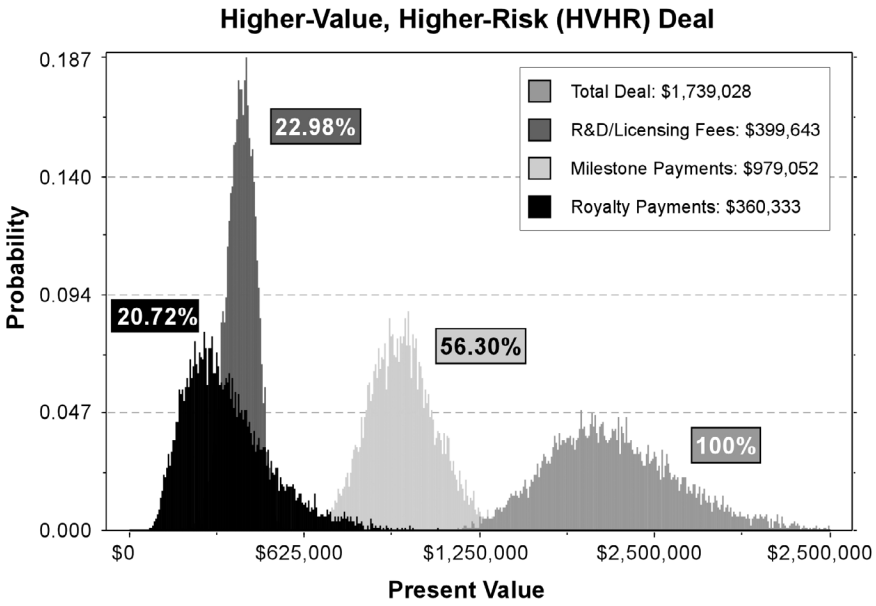

FIGURE 7.7 A comparative illustration III.
Illustrations of the Monte Carlo distributions for cash-flow present value of the HVLR deal scenario along with the distributions of the deal's individual components. Here, proportionally, milestones contributed the most to deal value (56.30 percent), followed by R&D/licensing (22.98 percent), while royalties contributed 20.72 percent to total deal value.

probability of IND filing produced the largest variation in the HVLR deal. The annual research cost for each FTE for the licensor performing the remaining preclinical work in preparation for IND filing was third, while the negotiated annual funding amount for each FTE was fourth. The value of each milestone was listed earlier in importance in comparison to the historical deal (Figures 7.4 and 7.8). This result should not be surprising as the present value of total milestones increased 93.6 percent over the historical structure.

The probabilities of completing various clinical trial stages were not clustered as with the historical deal (Figures 7.4 and 7.8). Indeed, the probability of completing Phase 1 was 2nd, the probability of Phase 2 completion 5th, and the probability of Phase 3 completion 10th in predicting variation in total HVLR deal value (Figure 7.8), whereas in the historical deal, these three variables were clustered and ranked 4th through 6th (Figure 7.4). This reorganization is probably because of milestone restructuring where, in the HVLR deal structure, early milestone payments are worth much more (Table 7.1 and Figure 7.1). Among the top 20 most important

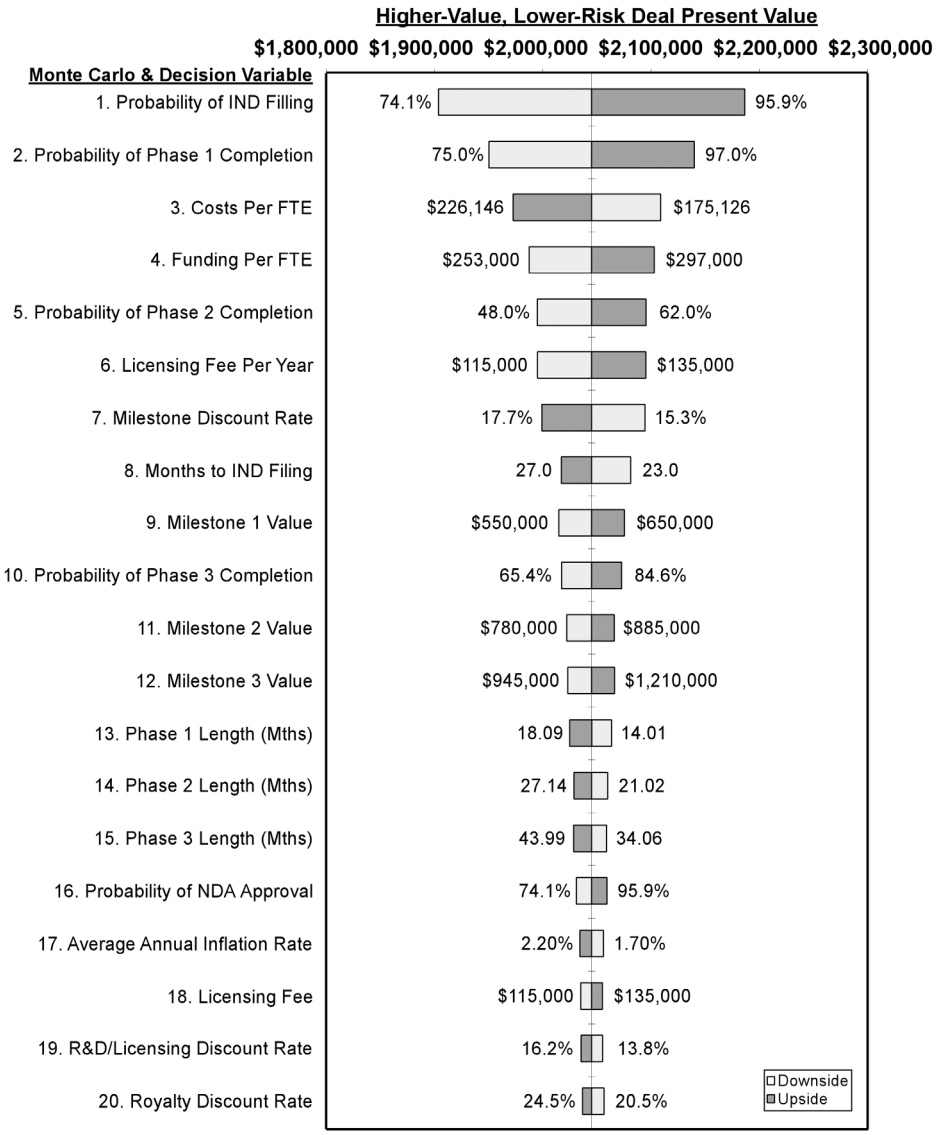

FIGURE 7.8 Higher-value, lower-risk deal scenario Monte Carlo tornado.

variables inducing variation in the HVLR deal are the lengths of Phase 1, Phase 2, and Phase 3 clinical trials (13th–15th; Figure 7.8), although their importance was considerably less than the historical deal (Figure 7.4). This is probably because of the reduced royalty component of the HVLR scenario (Table 7.1).

Higher-Value, Higher-Risk Deal Valuation

Changes in Key Assumptions and Parameters Differing from the Historical and HVLR Deal Structures A variety of financial terms were changed for the HVHR deal structure. First, licensing and licensing maintenance fees were reduced, sometimes substantially (Table 7.1). R&D fees were reduced across the board from the historical deal and the milestone schedule was completely restructured. The historical structure had three payments and the HVLR structure five, with the HVHR deal having only four (Figure 7.1). As shown, the milestone future value for the HVHR deal was reduced to $5,850,000 from $6,000,000 in the historical deal. Like the HVLR deal, the milestone values for the HVHR scenario were stochastically optimized based on specific ranges. The sacrifices gained by lower licensing fees, R&D funding, and milestone restructuring were compensated for by a higher flat royalty rate of 5.5 percent of net sales (Table 7.1).

Deal Valuation, Statistics, and Sensitivities Figure 7.7 shows an illustration of the total HVHR deal along with its three components. Total deal value for the HVHR scenario was $1,739,028, a 21.4 percent increase from the historical deal and 16.9 percent decrease from the HVLR structure. R&D/licensing present value decreased by 44.7 percent and 57.4 percent from the historical and HVLR deals, respectively (Figures 7.3 through 7.7).

The royalty distribution is much more pronounced and noticeably positively skewed, and illustrates the large downside potential of this deal component. Changes in the royalty percentage also significantly expanded the range maximum for the total deal ($3,462,679) with a range width of $2,402,076, a 130.4 percent increase from the historical and 84.6 percent increase over the HVLR deal widths, respectively (Table 7.2).

Milestone present value increased by 69.1 percent from the historical deal and decreased 12.6 percent from the HVLR scenario, while royalty present value increased 175 percent and 1,002 percent, respectively (Figures 7.3 through 7.7). Both the skewness and kurtosis of total deal value under the

TABLE 7.2 Deal Scenario Summary Table as Calculated by Monte Carlo Analysis

Deal Structure	Expected Value	CV	Range Minimum	Range Maximum	Range Width
Historical	$1,432,128	9.38%	$ 994,954	$2,037,413	$1,042,459
Higher-Value, Lower-Risk	2,092,617	7.85	1,475,620	2,777,047	1,301,427
Higher-Value, Higher-Risk	1,739,028	14.33	1,060,603	3,462,679	2,402,076

HVHR scenario were greater than the other deal structures evaluated (Figures 7.3 through 7.7). This result has to do with the greater royalty component in the HVHR scenario and its associated large cash-flow volatility.

The overall deal risk under the HVHR scenario was the greatest (14.33 percent) in comparison to the historical deal's 9.38 percent and the HVLR scenario's 7.85 percent cash-flow CV, again illustrating the strong royalty component of this deal structure with its greater volatility. With the HVHR deal, R&D/licensing cash flows had much higher risk than either the historical or HVLR deals (data not shown). This increased risk is surely because negotiated R&D funding per FTE and licensing fees were considerably less than the estimated cost per FTE, resulting in more R&D/licensing cash-flow volatility in the HVHR structure. This result again shows the importance of accurate accounting and finance in estimating R&D costs for maximizing this type of licensing deal value.

Monte Carlo Assumption and Decision Variable Sensitivities The tornado chart for the HVHR deal scenario emphasized the importance of variables directly impacting royalty cash flows (Figure 7.9). Here, the royalty discount rate was 4th, manufacturing and marketing offset 5th, and maximum market share capture 6th in impacting total deal present value variation. Total market size and the average APPI were 11th and 12th, respectively. Interestingly, the negotiated royalty percentage was only 19th in contribution to deal variance. Cost per FTE ranked 8th, showing this assumption is important in all deal scenarios (Figures 7.4, 7.8, and 7.9). Figure 7.10 shows the Monte Carlo simulation results for HVHR.

The negotiated first milestone value was the only milestone listed on the sensitivity chart (13th, Figure 7.9), illustrating the importance of milestone structuring (Table 7.1 and Figure 7.1). The first milestone is impacted the least by the time value of money and the probability of completion of each clinical trial stage.

A Structural Comparison of Deal Scenario Returns and Risks

Total deal expected value and risk as measured by the CV of cash-flow present value are shown in Table 7.2. As illustrated here, higher expected value is not necessarily correlated with higher risk, which is contrary to a basic principal in finance where investments of higher risk should always yield higher returns. Thus, these data show why quantitative deal valuation and optimization is critical for *all* companies as higher deal values can be constructed with significantly less risk.

Also shown in Table 7.2 are the range minimums, maximums, and widths of the total deal value distributions as calculated by Monte Carlo analysis

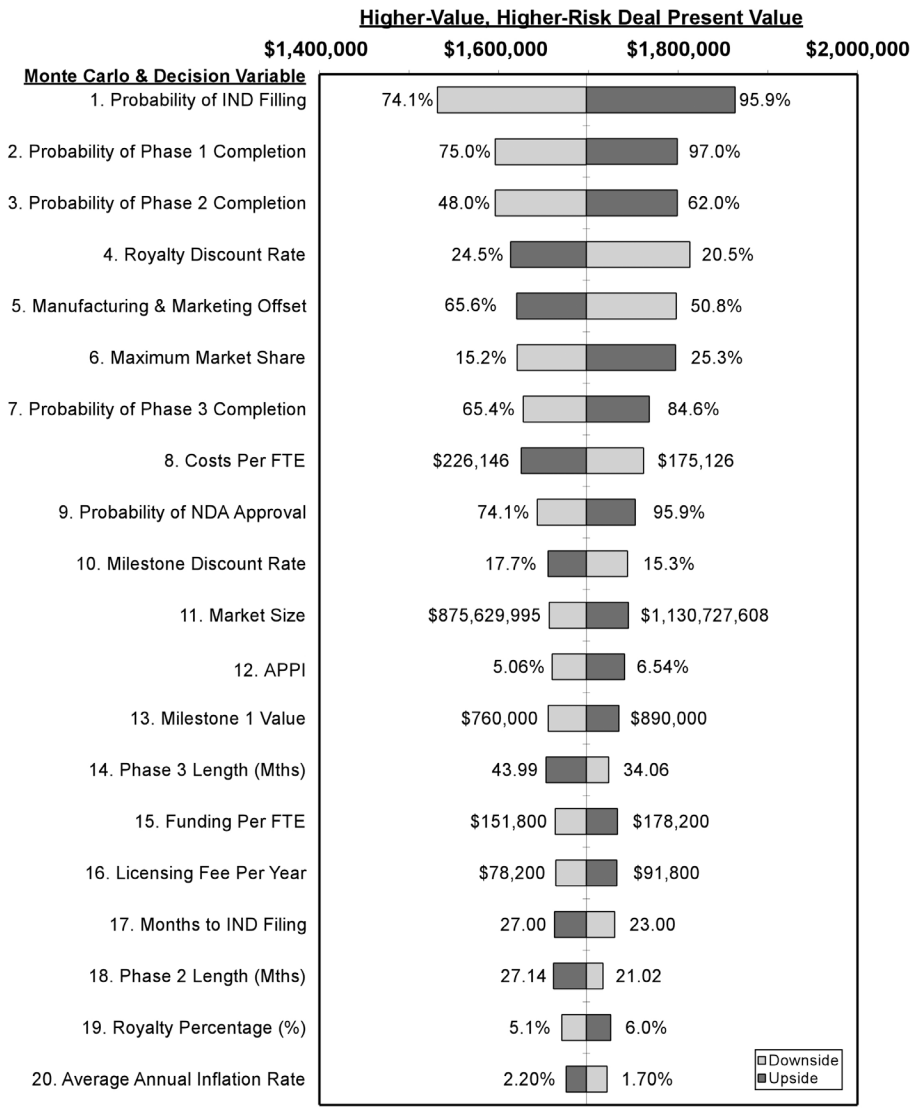

FIGURE 7.9 Higher-value, higher-risk deal scenario Monte Carlo tornado.

for each scenario evaluated. The range minimum is the smallest number and the range maximum the largest number in a distribution, while the range width is the difference between the range minimum and maximum.

Collaborative business deals in the biotechnology and pharmaceutical industries formed during strategic alliances, such as the one described here, are

Certainty is 50.00% from $1,563,891 to $1,882,975.

Summary

Certainty level is 50.00%.
Certainty range is from $1,563,891 to $1,882,975.
Display range is from $1,132,837 to $2,396,924.
Entire range is from $1,060,603 to $3,462,679.
After 10,000 trials, the standard error of the mean is $2,493.

Statistics

Trials	10,000
Mean	$1,739,028
Median	$1,712,532
Standard Deviation	$249,257
Variance	$62,129,317,618
Skewness	0.77
Kurtosis	4.39
Coefficient of Variability	14.33%
Range Minimum	$1,060,603
Range Maximum	$3,462,679
Range Width	$2,402,076
Mean Standard Error	$2,492

FIGURE 7.10 Higher-value, higher-risk deal scenario Monte Carlo summary.

in fact risky asset portfolios. As such, the standard deviation of a portfolio of assets is less than the weighted average of the component asset standard deviations. To view the impact of diversification of cash-flow streams with the various deal scenarios evaluated in this case study, the weight of each deal component was determined and the weighted average CV of cash-flow present value calculated for each deal scenario (Table 7.3). The CV is used as the primary risk measure because of differences in the scale of the cash flows from individual deal components.

As expected with a portfolio of risky assets, the weighted average of the CV of individual deal components (R&D/licensing funding, milestone payments, and royalties) was always greater than the CV of the total deal present value, illustrating the impact of diversification (Table 7.3). Thus, portfolios of less than perfectly correlated assets always offer better risk–return opportunities than the individual component assets on their own. As such, companies would probably not want to completely forgo receiving milestone payments and royalties for only R&D funding and licensing fees, *if* these deal components can be valued and optimized with reasonable accuracy as described here. By combining assets whose returns are uncorrelated or partially correlated, such as cash flows from milestone payments, royalties, licensing, and R&D funding, risk is reduced (Table 7.3). Risk can be eliminated most rapidly while keeping expected returns as high as possible if a

TABLE 7.3 Deal Component Weights, Component CVs, Weighted Average Deal CVs, and Calculated Deal CVs

	Weights			Coefficient of Variation (CV)				
Deal Structure	$W_{R\&D}$[a]	W_{Mi}[b]	W_{Ry}[c]	R&D[d]	Milestones	Royalties	W. Avg.[e]	Calculated[f]
Historical	50.42%	40.42%	9.17%	7.47%	14.57%	45.70%	13.84%	9.38%
Higher-Value, Lower-Risk	44.88	53.56	1.56	5.79	13.18	45.95	10.38	7.85
Higher-Value, Higher-Risk	22.98	56.30	20.72	13.40	12.69	46.21	19.80	14.33

[a]Proportion of total deal present value attributable to R&D and licensing fees.

[b]Proportion of total deal present value attributable to milestone payments.

[c]Proportion of total deal present value attributable to royalty payments.

[d]CV in the present value of cash flows from R&D and licensing fees.

[e]Weighted average of the CV of total deal value.

[f]Calculated deal CV by Monte Carlo simulation.

company's cumulative deal repertoire is valued, structured, and balanced from the beginning of a company's evolution and development.

Discussion and Conclusion

The historical deal evaluated in this case study was a preclinical, product-licensing deal for a biopharmaceutical with one major therapeutic indication. For collaborative deal structures containing licensing fees, R&D funding, milestone payments, and royalties, each deal component has definable expected values, variances, and widely varying risk characteristics. Alternative deal structures were developed and optimized, all of which had different expected returns and risk levels with the primary risk measure being the CV of cash-flow present values. Thus, nearly any biomedical collaborative deal with the types of financial terms described here can be quantitatively valued, structured, and optimized using financial models, Monte Carlo analysis, stochastic optimization, real options, and portfolio theory.

During this study, the author was at a considerable disadvantage because the historical deal valued and optimized here had already been signed, and he was not present during the negotiation process. Therefore, the author had to make a large number of assumptions when restructuring the financial terms of the agreement. Considering these limitations, this case is not about what is appropriate in the comparative financial terms for a biomedical licensing deal and what is not; rather, the data described here are valuable in showing the quantitative influence of different deal structures on the overall valuation of a biomedical collaborative agreement, and most importantly on the level of overall deal risk, as well as the risk of the individual deal components. The most effective approach using this technique is to work with a negotiator during the development and due diligence, and through the closing process of a collaborative agreement. During this time, data should be continually gathered and the financial models refined as negotiations and due diligence proceed.

CASE STUDY: OIL AND GAS EXPLORATION AND PRODUCTION

This case study was contributed by Steve Hoye. Steve is an independent business consultant with more than 23 years of oil and gas industry experience, specializing in Monte Carlo simulation for the oil and gas industry. Starting with a bachelor of science degree from Purdue University in 1980, he served as a geophysicist with Texaco in Houston, Denver, and Midland, Texas, before earning the MBA degree from the University of Denver in 1997. Since then, Steve has held leadership roles with Texaco as the midcontinent