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# **R&D Project Valuation and Licensing Negotiations at Phytopharm plc**

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— July 2006 —

# **R&D Project Valuation and Licensing Negotiations at Phytopharm plc**

## **Abstract**

We describe an R&D project valuation model developed for Phytopharm plc, an emerging pharmaceutical company based in Cambridge, UK. The model allows the company to value the projects in its R&D portfolio, and is used for licensing negotiations with potential product development and marketing partners. It is based on different valuation methods, including Net Present Value, Decision Analysis and Monte Carlo Simulation. We take into account the technological risks during the development phases of pharmaceutical products, as well as the uncertainty in terms of commercial success. In addition to determining a value for a product in development, the model also proposes appropriate contract structures for licensing purposes. A typical pharmaceutical licensing contract specifies milestone payments and royalties, to be paid by the licensee to the licensor. The contract structures adhere to an agreed-upon equitable split of the project value between the two parties. The model also generates critical information during the negotiation meetings in terms of break-even analyses, trade-offs and bargaining zones. It was used by Phytopharm during 2004 in its licensing negotiations for a novel product for the dietary control of obesity, which was licensed in December 2004 to Unilever, a multinational food company. Phytopharm is currently deploying the model for its entire project portfolio.

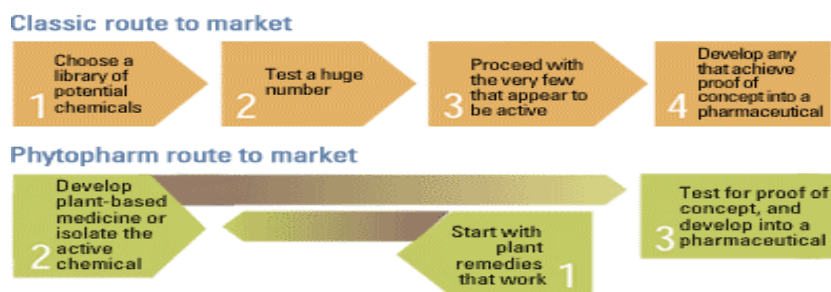
## **Keywords**

Project Valuation, Negotiation, Pharmaceuticals, Decision Analysis, Monte Carlo Simulation, Real Options

## Introduction

The structure of the pharmaceutical industry is changing as many large pharmaceutical companies struggle to fill their product pipeline. Rather than relying on in-house research projects, these companies rely more and more on small biotechnology companies to provide innovation and novel therapeutic approaches, resulting in an increase in the number of licensing deals. This allows the major pharmaceutical companies to focus on their core strengths such as manufacturing, distribution, marketing and sales. For instance, in 2002, Merck reviewed thousands of licensing opportunities, and completed on 32 deals (Drug Week, 2003). Meanwhile, several factors have contributed to the rise in the cost of pharmaceutical development beyond the capabilities of most smaller companies, including (a) tighter regulation, which has led to increasing development costs, (b) dedicated and sophisticated production facilities required by the new generation of biochemical pharmaceuticals, and (c) huge marketing efforts necessary for a successful world-wide launch of new products. This evolution has prompted smaller companies to turn to the major players in the industry and to offer licensing opportunities.

Phytopharm plc is an emerging pharmaceutical company, based in Cambridge, UK and listed on the London Stock Exchange, established in 1990 and floated in 1996. The company specializes in the discovery and development of plant-based medicines, examining plants with an anecdotal history of clinical benefit (Figure 1). Phytopharm is working in four disease areas, namely the *neurodegeneration* area targeting Alzheimer's, Parkinson's and motor neuron diseases, the *metabolic disease* area focusing on obesity and metabolic diseases, *dermatology* and *inflammation*. Phytopharm actively tries to reduce its risk exposure by out-licensing its products in development, and seeking early commercialization of secondary products, such as food and veterinary products. Phytopharm's extensive recourse to outsourcing of the laboratory work and clinical testing to specialists, and the systematic licensing of its projects once proof of principle is passed, allows it to maintain a strong focus on its core competencies, namely pre-clinical and clinical strategy and management.



**Figure 1.** Phytopharm's R&D strategy compared to the classic pharmaceutical route to market.

Phytopharm typically performs the first steps of pharmaceutical research: isolating the active compound, identifying the mode of action, and taking the novel compounds through the pharmaceutical development process until the successful completion of proof of principle, i.e. the pre-clinical and toxicology phase and Phase I and II clinical trials. If proof of principle is achieved, Phytopharm licenses the project out to large pharmaceutical partners that have the financial, R&D and marketing resources to further develop and launch the product. Phytopharm's revenues consist entirely from licensing agreements for their projects. A licensing deal typically contains a downpayment at contract signature, lump sum payments on successful completion of specific milestones and royalties on sales. The strategic emphasis on risk reduction means that Phytopharm has a preference for downpayments and milestone payments.

When Phytopharm's management team contacted us in October 2003, they were preparing to start negotiations for the *Hoodia gordonii* extract, a new product for the dietary control of obesity. Phytopharm had acquired the exclusive license to develop and market a natural appetite suppressant derived from the *Hoodia gordonii* succulent, which grows in the African Kalahari desert. Hoodia species have been used by the Xhmani San people for centuries as a food of last resort to stave off hunger and thirst. Examining this plant, the South African Council for Scientific and Industrial Research discovered the appetite suppressant properties of *Hoodia gordonii* extract and recognized the extract's potential as an anti-obesity agent. The patented extract was licensed to Phytopharm in 1997, who developed a pharmaceutical product based on *Hoodia gordonii* extract that successfully achieved proof of principle in clinical trials of healthy overweight men in 2001.<sup>1</sup>



**Figure 2.** *Hoodia gordonii* cultivated by Phytopharm for the DCO product.

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<sup>1</sup> Interfaces, INFORMS and the authors have no opinion on the scientific case for or against Hoodia Gordonii, nor have the claims of Phytopharm regarding the effectiveness of Hoodia Gordonii been reviewed for the purpose of this article, which only describes the use of decision tools in aiding R&D licensing negotiations.

To enhance revenues and reduce risk, Phytopharm pursued a differentiation strategy, pitching the product at two different markets. On the one hand, research was conducted to manufacture the plant derived active compound synthetically. Though this is a complex and expensive process, it allows cheap bulk production and targeted improvement of the molecule, making it ideal for the pharmaceutical industry as a prescription drug. On the other hand, Phytopharm was developing a botanical product for use as a food additive. Both applications were covered by patents. The natural compound is covered until 2018, though a new filing has been made that should extend protection until 2025. In May 2004, Phytopharm was preparing to start negotiations for the botanical product with multinational food companies. Even though management was confident that this could be a blockbuster product, i.e. with annual sales over US\$1 billion, Phytopharm needed to have a comprehensive and flexible methodology to predict and value the product's potential in a rigorous way. Also, Phytopharm wanted a model to support the licensing negotiations for their products – the determination of upfront payments, milestone payments and royalties – and enable it to appraise the value of its projects, to improve shareholder value and portfolio management.

This paper presents the model we have developed for Phytopharm. Throughout the text we combine the description of the model with an account of our relations with Phytopharm and the model's impact on project valuation and negotiation. The first section provides background information on the pharmaceutical development process, and highlights the consequences for this particular DCO product. The second section provides details on the valuation model. The third section briefly describes the sensitivity and simulation functionalities included in the model and the fourth section presents the tools designed to support Phytopharm in their negotiations. Before concluding, we report on Phytopharm's use of the model, internally and externally.

A study for a similar product is presented in Ruback and Krieger (2000), where a decision analysis model is proposed to value a licensing opportunity, using the given project parameters. We add to this by performing the complete model cycle: problem definition, data collection, model design, project valuation, sensitivity analysis, negotiations support and implementation of the model in practice. Other papers present a real options approach to project valuation (Hearth and Park, 1999; Lewis, Enke and Spurlock, 2004). However, these papers mainly present theoretical developments and may not be directly accessible to practitioners as they do not provide details on how to develop such a model and on the impact of the application of the valuation methodology. For a comprehensive review on optimal models for licensing, we refer to Crama, De Reyck and Degraeve (2005).

## The Pharmaceutical Development Process

Pharmaceutical development is a risky, time-consuming and expensive process. The average time from compound to market has grown from 8.1 years in the 1960s, to 11.6 years in the 1970s, to 14.2 years in the 1980s and 1990s (DiMasi, 2001). Lengthening development times also increase development costs; recent estimates indicate that the cost of developing a medicine is around \$900 million (DiMasi et al., 2003), which includes expenditures on failed products. Newly developed medicines are protected by patents, typically for 20 years, although in practice this results in a post-regulatory approval patent life of approximately 12 years.

The pharmaceutical registration process is heavily regulated. Stringent scientific procedures have to be followed to ensure patient safety in distinct stages, including pre-clinical and clinical tests, before a medicine can be approved for production and marketing. The pharmaceutical development process in the United States is monitored by the U.S. Food and Drug Administration (FDA). Comparable institutions exist in other countries around the world, like the European Agency for the Evaluation of Medicinal Products (EMA), which grants marketing authorization for the EU. The pharmaceutical development and review process is typically as given in Table 1.

<i>Phase</i>	<i>Typical duration</i>	<i>Probability of advancing to next stage</i>	<i>Probability of FDA approval</i>	<i>Proportion of total R&amp;D costs (including failed products)</i>
<i>Basic Research</i>	2 years	0.4%	0.02%	24%
<i>Pre-Clinical</i>	3 years	25%	5%	12%
<i>Clinical I, II, III</i>	6 years	25%	20%	29%
<i>FDA Review</i>	1-2 years	80%	80%	35%

**Table 1.** The typical pharmaceutical development and review process takes a substantial number of years and carries a high risk of failure.

On average, only one in five medicines entering clinical trials is launched, and only one in five thousand compounds in the research phase makes it to the market. As a consequence, a large portion of all development costs is spent on medicines that never reach the market, illustrating the high technical risks involved. In addition, of those medicines that are commercialized, only 30% achieve the commercial success necessary to recover the (after-tax) development costs to yield a healthy return, illustrating the additional commercial risks involved (Grabowski et al., 1994). Nevertheless, pharmaceutical companies in recent years have been able to report healthy profits, of about 20% on gross revenues.

Phytopharm hoped the FDA would grant the functional food product “GRAS” (generally recognized as safe) status, which was thought to be a way of achieving robust label claims.

Phytopharm's strategic focus on plant derived products with anecdotal evidence of clinical benefit produces novel products with potentially lower development risk in terms of both efficacy and safety. Since the pharmaceutical grade botanical extract had shown statistically significant reductions in calorie intake in early clinical trials, marketing a food grade botanical extract as a functional food in combination with nutrients and calories seemed to be the most natural method of delivering the product to consumers in an effective but safe way. As a result, Phytopharm was negotiating with food companies as potential licensees, and it was feared that they would not be familiar with the particular product development processes, and that this might create some problems during the negotiations.

## **The Valuation Model**

### **General features**

We have developed a model that allows valuing the projects in Phytopharm's portfolio using Net Present Value, Decision Analysis and Monte Carlo simulation. The model also enables the valuation of different licensing contracts and payment structures based on milestone payments and sales royalties, by computing the Net Present Value provided by the contract for Phytopharm and the potential licensee, and analyzing how the risk is shared between the two parties. The model assists Phytopharm's management in its negotiations when discussing licensing deals for its products in development.

Phytopharm contacted us after a consulting agency delivered a valuation model that worked as a black box, with which they did not feel comfortable. Therefore, our model was built with three main features in mind: transparency, parameterization and flexibility. First, Phytopharm requested a transparent model and wanted to avoid the black-box phenomenon often associated with externally developed models. This is particularly relevant in this context where Phytopharm management wanted to present the model to licensing partners, and to make it a credible basis for negotiation. Second, extensive use of parameterization in the model was essential, allowing the negotiation partners to discuss the assumptions underlying the valuation model, and to change the settings during the negotiations, with immediate effect on the valuation results. In an effort to improve understanding, many of these parameters required an intuitive graphical representation in the model. Finally, as Phytopharm conducts negotiations for several different projects, management wanted a model that would be sufficiently generic and flexible and that could be used for different projects.

The valuation model is built in Excel using Visual Basic for Applications (VBA), with a separate add-in for Risk Analysis and Monte Carlo Simulation. We used @Risk for Excel, developed by Palisade Corporation ([www.palisade.com](http://www.palisade.com)). The layout of the spreadsheets in the model was carefully



designed according to the principles of good spreadsheet design (Powell and Baker, 2004), contributing considerably to an enhanced transparency of the model.

### **Development Stage Model**

We will describe how the model was used to value the ‘dietary control of obesity’ project, or *DCO project*, in Phytopharm’s portfolio. Although the DCO product will be a functional food product, its development follows the same project structure as a typical pharmaceutical product. Phytopharm had already achieved proof of principle for the original botanical pharmaceutical product after successfully completing the pre-clinical and clinical phases I and II, but was seeking to attract a licensing partner to develop and market the DCO product. The project is composed of two distinct parts: (a) the R&D stage, consisting of a basic research stage and a development stage including pre-clinical and clinical trials, manufacturing and pre-launch marketing, and (b) the market stage, following the market introduction.

The R&D stage was fully documented by Phytopharm who submitted a detailed project plan to its negotiation partners. A part of the project plan is shown in Figure 3.<sup>2</sup> The cost and timing parameter estimates in the model are derived from this plan, and can be changed in real time during the negotiations, to examine their impact on the project value. The project stages are also derived from the project plan, and are agreed upon by both parties. Theoretically, it should be in the interest of both parties to identify as many milestones as possible, as this increases the number of abandonment options included in the project. However, during the negotiations, we noticed a diverging agenda for both parties. Phytopharm typically prefers to keep the number of stages small because that seems to increase the negotiation partner’s estimate of the project’s overall probability of technical success (PTS). The reason for this is that very often, the negotiation partner does not have an overall PTS in mind that is allocated to the different project phases, but assigns a certain probability per phase that then combines into the overall PTS. This second approach tends to yield a lower overall PTS when the number of phases is high. Thus, both the number of stages and the PTS of each stage are an integral part of the negotiation process and are based on estimates by experts at Phytopharm, using historical data adapted for the specificities of the project under evaluation.

The R&D stage consists of a series of development phases, and for each phase the model captures the development cost, probability of success and start and end dates. Initial marketing costs incurred before launch are also attributed to the appropriate phase. In the model, the project is represented as a decision tree, in which a new phase will only be started if the previous phase was successful, and the project will only be successful if all its phases are successful.

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<sup>2</sup> All the data reported in this paper concerning the DCO project is disguised.

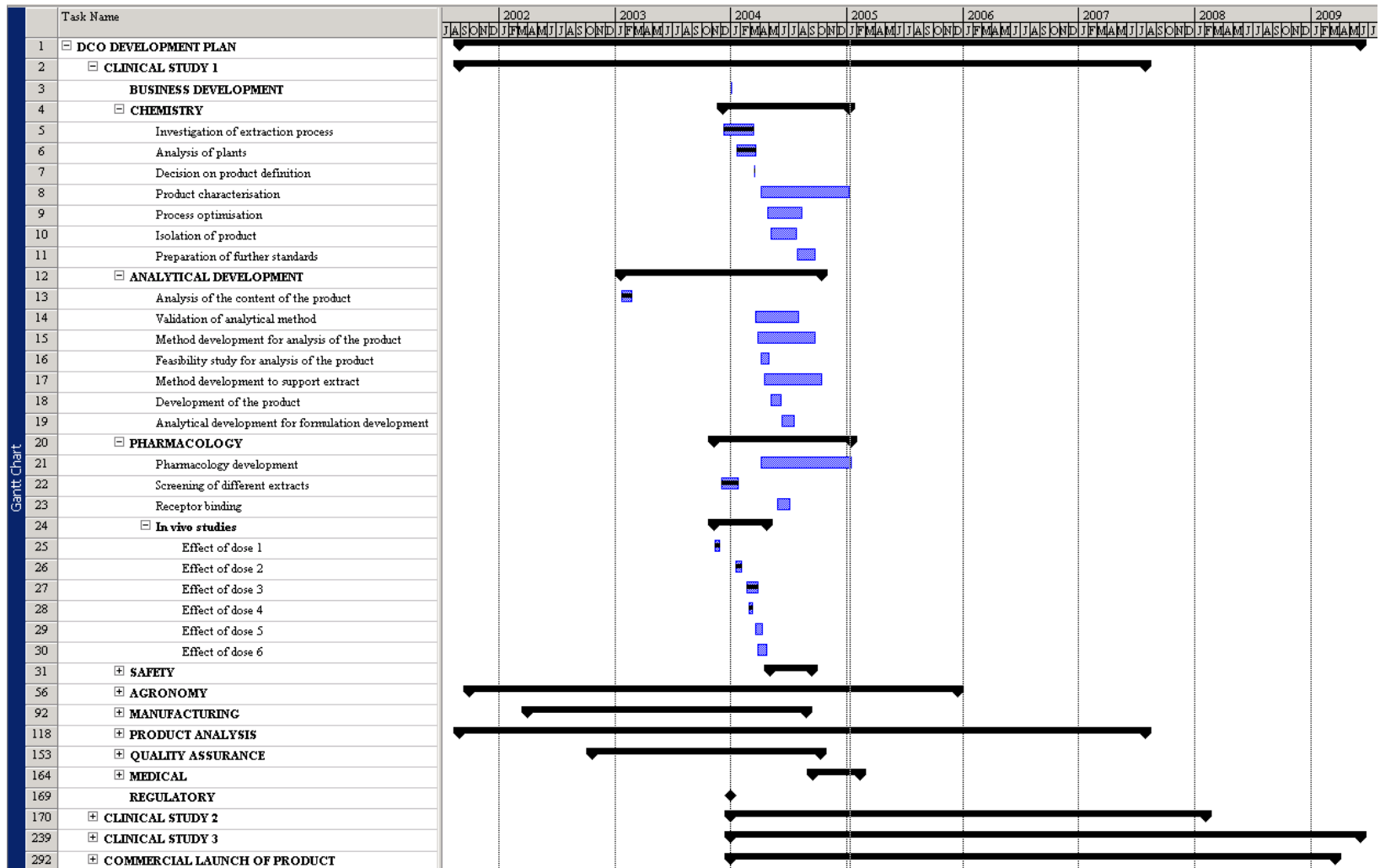
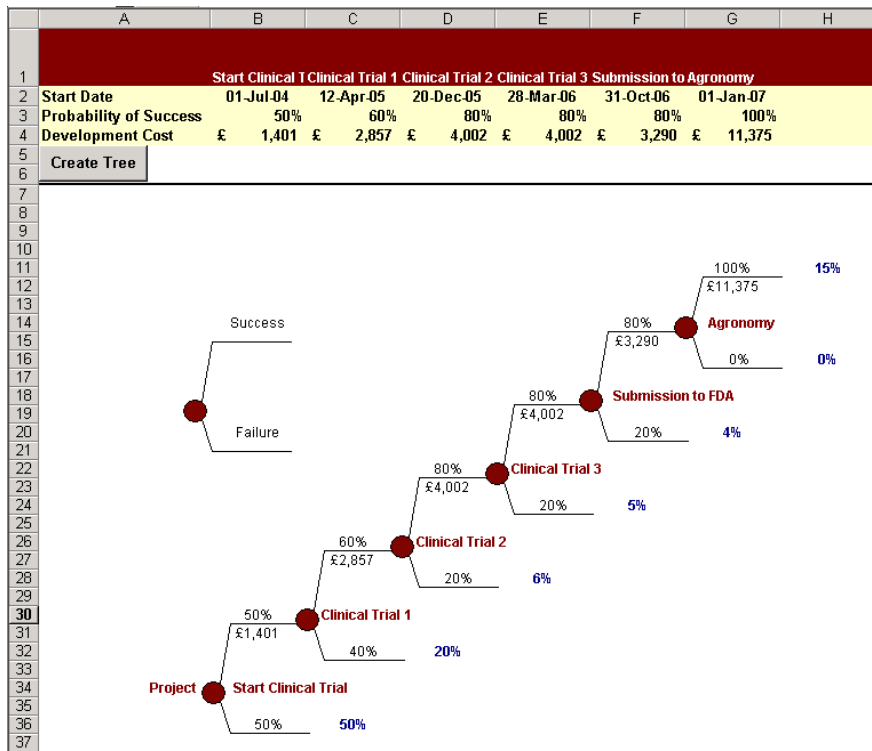


Figure 3. The DCO project plan contains details on the timing and cost of each of the project phases and activities (disguised data).

Since the number of stages was an outcome of initial discussions, it was important to make it flexible in the model and allow Phytopharm to change it interactively. To facilitate this, we included in the model a graphical representation of the resulting decision tree (Figure 4). Note that in this project, failure automatically forces the termination of the entire project, whereas success implies continuation. Decision nodes could be added to model additional options.

The launch date for this project is set for early 2007. Given the limited patent life, a delay in the product launch can be very costly in terms of lost sales. Conversely, it is interesting to note that even though reducing the project duration may be an attractive proposition, yielding longer monopoly profits, working with natural compounds makes it more difficult to do so as a minimum time is required for the plants to grow to maturity.



**Figure 4.** A decision tree is used to present the project structure, and includes information regarding timing, cost and probabilities of technical success for each of the project phases. The decision tree is drawn automatically at the push of a button (disguised data).

### Market Stage Model

The DCO product in its food product version is designed to target the meal replacement and nutritionals market, which includes calorie-controlled meals, bars, powders and beverages. The product would be launched first in the US, the world’s largest healthcare market. In 2003, the US meal replacement market reached a total value of approximately \$1.5 billion, with steady double-digit

growth rates over the past several years. Phytopharm provided us with their own sales estimates, based on the population of obese, overweight and diabetics. However, their standard valuation approach would be difficult to defend in negotiations.

In order to derive credible estimates of future demand, we developed a model that was consistent with the custom in the pharmaceutical industry, where standard growth curves are typically used to generate sales forecasts, with S-curves being the most prevalent type. The advantage of these curves is the flexibility that they offer to generate different growth patterns and product life cycles. Initially, we considered a Bass curve (Bass, 1969), which models the diffusion of a new product in a market and is widely used in practice. However, that model does not look at the individual brand level, and thus does not acknowledge the impact of competitor entry on branded product sales. As long as the product is protected by patents, this is a fair representation of reality. However, as soon as competitors enter the market, they may take over a substantial share of the market. Therefore, we developed a sales forecasting model based on the number of people purchasing meal replacement products, using a modified version of the trial-repeat model of Lilien, Rao and Kalish (1981), which explicitly allows for switching between brands. The model estimates the evolution in sales by modeling the number of potential clients trying out the product, then becoming repeat purchasers and finally switching brands, holding the average expenditure on the product constant. It can be expressed as follows:

$$\begin{aligned} x_t &= \min\left(z_t - X_{t-1}; (y_1 e_{t-1} + y_2 e_{t-1}^2)(\bar{X} - X_{t-1}) - y_3 \bar{e}_{t-1} X_{t-1} + w(x_{t-1})(\bar{X} - X_{t-1})\right) \\ X_t &= X_{t-1} + x_t \\ s_t &= f \cdot X_t \end{aligned}$$

where  $x_t$  are the new adopters in period  $t$ ,  $X_t$  the cumulative number of users in period  $t$  and  $\bar{X}$  the size of the target market of the product. The parameter  $e_t$  represents the marketing effort with decreasing marginal returns ( $y_2 < 0$ ),  $\bar{e}_t$  is the marketing effort for competing products and  $w(x_t)$  is the word-of-mouth effect, a linear function of the number of new adopters. The parameter  $\bar{e}_t$  is zero before competitor's entry, and is strictly positive thereafter, which allows to model a sudden drop in sales at the time of patent expiry. Sales  $s_t$  are computed by multiplying the total number of users by the average expenditure  $f$  per user. The parameters shaping the sales growth curve are  $y_1$ ,  $y_2$ ,  $y_3$ ,  $\bar{X}$  and the year in which competitors enter the market. Using these five parameters, several different shapes for the sales growth curve can be obtained, ranging from standard S-shapes to shapes including a drop in sales after patent expiry.

Additionally, we have extended the model to include capacity constraints. Such constraints are highly relevant for organically-grown products, such as the DCO product, that require an agronomy

phase during which the product is farmed and harvested, and for which production capacity can only be gradually created. Therefore, there is a distinct possibility that Phytopharm will not be able to fully meet demand for the product in the early years. The model allows specifying a limit  $z_t$  on the number of people who can be served each year. A binding capacity constraint results in reduced sales in the year in which capacity is reached, but also has an indirect effect on sales in subsequent periods since fewer people try out the product, reducing the word-of-mouth effect.

We have made initial estimates of these parameters based on data retrieved from market research reports, which estimate the market potential for meal replacement products as approximately 15 million people, spending on average \$140 per year on slimming products (MarketData Enterprises, 2002). Once more, the market data parameters can be changed during the negotiation, and can be driven by the potentially superior market knowledge of the negotiation partner. We therefore decided to build the model so as to allow that flexibility in an intuitive way with immediate graphical representation of the consequences of each parameter on the sales estimate. In the sensitivity analysis, we also allow for uncertainty on these estimates in the form of ranges. An additional reason to keep the sales model as general as possible was that Phytopharm typically negotiates with several parties in very different industries. Patent expiry is a major issue in the pharmaceutical industry, but not necessarily in the food industry – and in both cases, brand name building can mitigate the effects on sales. Even within the same industry, different companies operate under different market situations. Unilever, for example, already owns a range of slimming products, and does not face the same challenges at product introduction since it can incorporate the compound into its existing brand and thus bypass the slow adoption process.

Our model allows sales forecasts up to a horizon of 25 years, with a terminal value capturing the present value of a perpetuity based on sales in year 25. Based on our discussions with the CEO and CFO, as well as the marketing manager, we have opted for a slightly longer time horizon than the patent life because many pharmaceutical companies actively engage in brand name recognition in order to prevent the drastic sales decline that the loss of patent protection often entails.

Figure 5 shows the “Sales” sheet for the DCO product, which contains information on sales forecasts and related expenditures. The following information needs to be entered (cell references between brackets): launch date (D2); the market size or target population, in this case, the number of people buying meal replacement products (D4); peak market penetration rate as a percentage of the total target population (D5); market growth (D6); the percentage of initial adopters (D7); the average spend per customer (D8); and the date of competitor entry or patent expiry (D11). The first scrollbar (D9) allows to specify the take-up speed after launch. In our sales model, this corresponds to the pair of values  $(y_1, y_2)$ . The second scrollbar (D12) determines the sales decay after competitor entry, which depends on the impact of competitor’s advertising,  $y_3$ . These scrollbars allow a wide variety

of sales growth curve shapes to be modeled. The curve displayed on the sheet in Figure 4 changes automatically when parameter values are changed, allowing the user to visually assess the impact of parameters settings on the sales curve. This reduces the difficulty of setting parameters and allows to mould a sales curve that fits the expectations of both negotiating parties. The time to reach peak sales is automatically computed (D10). Finally, information is required on the available capacity in each year (row 14), as well as on the required annual marketing expenditures (row 15). The resulting sales estimates are reported in the bottom row of the sheet (row 19).

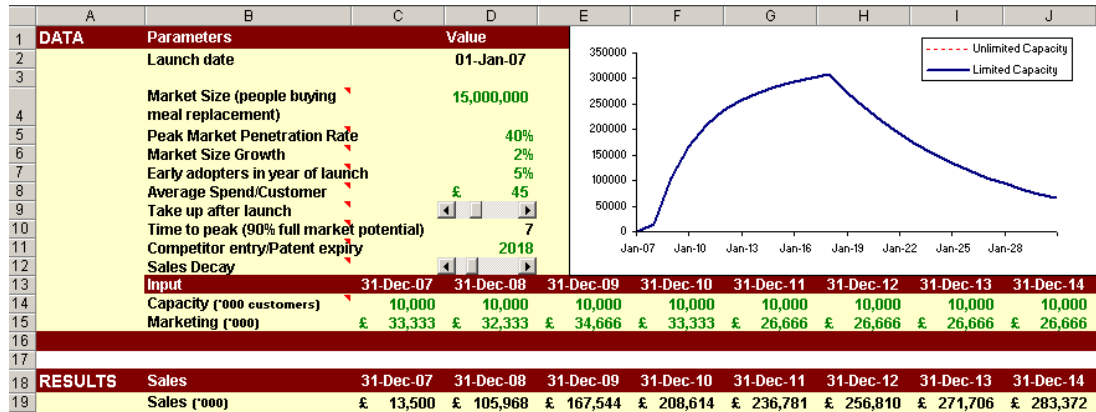


Figure 5. The “Sales” sheet allows specifying a sales growth curve (disguised data).

## Project Valuation

Based on the project structure and sales forecasts, the Net Present Value (NPV) of the project can be computed using standard NPV calculations. The project’s discount rate can be set equal to the company’s Weighted Average Cost of Capital (WACC), or to any value agreed upon between the two parties. The structural elements of a contract between Phytopharm and a potential licensee are the milestone payments, to be paid after the successful completion of each project phase, and royalties, as a percentage of sales. When these payments are agreed upon, the NPV of the project is effectively divided between the two parties. Taking the contract terms into account, we can compute the licensor’s and the licensee’s NPV.

The core of the model is the “Valuation Model” sheet, which contains summary information on the project’s financials, its value and the value of the deal for Phytopharm and the licensee. The sheet is designed according to the principles of good spreadsheet design (Powell and Baker, 2004), and consists of three main sections, labeled “Data”, “Results” and “Model”. Figure 6 shows the “Data” section for the DCO project. It contains information on the required currency (C2), the anticipated launch date (C3), the operating margin (C4) and depreciation as a percentage of gross sales (C5), the tax rate for the licensee (C6) and Phytopharm (C7), the agreed-upon royalty as a percentage of gross

sales (C8), a provision for intellectual property (IP) rights to be paid by Phytopharm to a third party as a percentage on royalties (C9), the risk-free (long-term) discount rate (C10), a discount rate appropriate for the project, agreed by both parties (C11), or alternatively, the model automatically computes a discount rate for the project (C12), the licensee (C13) and Phytopharm (C14) based on the inherent risk in the project and the risk borne by each party.

The sheet also allows the input per project phase of the start date (row 16), the probability of success (row 17), an agreed-upon milestone payment at the start of each phase (row 18), IP rights to be paid by Phytopharm to a third party as a percentage of the milestone payment received (row 19), an estimate of the development cost (row 20) and pre-launch marketing expenditures (row 21), and an error indication showing a message if any of the inputs are missing or incorrect (row 22).

	A	B	C	D	E	F	G	H
1	<b>DATA</b>	<b>Parameters</b>						
2		Currency	£ (British Pound)					
3		Launch Date	01-Jan-07					
4		Profit Margin	50%					
5		Depreciation (% of sales)	0%					
6		Tax Rate (Client)	0%					
7		Tax Rate (Phytopharm)	0%					
8		Royalties	10%					
9		IP rights on Royalties	0%					
10		Risk-Free Discount Rate	5%					
11		Project Discount rate	11%					
12		Equivalent Discount Rate: Project	7.18%					
13		Equivalent Discount Rate: Client	7.77%			<input type="checkbox"/> Automatic Discount Rate		
14		Equivalent Discount Rate: Phytopharm	6.13%					
		<b>Project Phases ('000)</b>	<b>Start</b>	<b>Clinical</b>	<b>Clinical</b>	<b>Clinical</b>	<b>Submission</b>	<b>Agronomy</b>
			<b>Clinical</b>	<b>Trial 1</b>	<b>Trial 2</b>	<b>Trial 3</b>	<b>to FDA</b>	
15			<b>Trial</b>					
16		Start Date	01-Jul-04	12-Apr-05	20-Dec-05	28-Mar-06	31-Oct-06	01-Jan-07
17		Probability of Success	50%	60%	80%	80%	80%	100%
18		Milestone Payment	£ 1,000	£ 2,000	£ 2,000	£ 2,000	£ 2,000	£ 2,000
19		IP Right on Milestones	0%	0%	0%	0%	0%	0%
20		Development Cost	£ 1,401	£ 2,857	£ 4,002	£ 4,002	£ 3,290	£ 11,375
21		Pre-Launch Marketing	£ -	£ -	£ -	£ -	£ -	£ -
22		Error Indication						
23								

**Figure 6.** The DATA sheet contains information on the development stage of the project.

The “Results” section in Figure 7 contains summary information on the value of the project, and how the value is split between the two parties, Phytopharm and the licensee. The NPV for the project is reported (C26), with a breakdown for sales, operating profit, marketing expenditures and development costs. Additionally, based on the milestone payments and royalty percentage in the “Data” section, the NPV for Phytopharm (C32) and the licensee (C36) are given, with a breakdown, for Phytopharm, in milestone and royalties. For the licensee, an internal rate of return (C37) and payback period (C38) are also provided. The model also suggests a milestone payment based on the probability of technical success of each phase (row 41, more information below), along with an indication of the proposed milestone payment as a percentage of the suggested value (row 42).

The “Model” section in Figure 8 contains a profit and loss statement with annualized information on sales (row 50), cost of goods sold (row 51), marketing expenditures (row 52), development costs

(row 53), free cash flows (row 54) and an NPV value (C57). A terminal value (C56) is used to capture the revenues beyond the model horizon, i.e. more than 25 years after launch. For both parties, additional information on milestone payments (rows 65 and 75), royalties (row 76), IP rights (row 77) and depreciation (row 64) is also included, resulting in profits before and after taxes.

	A	B	C	D	E	F	G	H
25	<b>RESULTS</b>	<b>Net Present Value</b>	<b>Value</b>					
26		Project	£ 62,569					
27		Sales	£ 200,169					
28		Operating Profit	£ 100,084					
29		Marketing Cost	£ 31,127					
30		Development Cost	£ 6,389					
31		<b>Phytopharm</b>						
32		Milestones and Royalties	£ 23,391					
33		Milestones	£ 3,374					
34		Royalties	£ 20,017					
35		<b>Client</b>						
36		Project after Milestones and Royalties	£ 39,178					
37		Internal Rate of Return	31%					
38		Payback Period (years)	5.97 y					
39		<b>Project Phases</b>						
40				Start Clinical Trial	Clinical Trial 1	Clinical Trial 2	Clinical Trial 3	Submission to FDA
41		Value Created at Milestone	£ 22,380	£ 27,268	£ 41,112	£ 27,754	£ 41,015	£ 44,946
42		Milestone as % of Value Created	4%	7%	5%	7%	5%	4%
43								

Figure 7. The RESULTS sheet contains information on the value of the project for both parties.

	A	B	C	D	E	F	G	H	I	J
45	<b>MODEL</b>	<b>Project Income Statement &amp; Valuation</b>	Start Clinical Trial	Clinical Trial 1	Clinical Trial 2	Clinical Trial 3	Submission to FDA	Agronomy	Sales Year 1	Sales Year 2
46			01-Jul-04	12-Apr-05	20-Dec-05	28-Mar-06	31-Oct-06	01-Jan-07	31-Dec-07	31-Dec-08
47		Probability of getting to date	100%	50%	30%	24%	19%	15%	15%	15%
48		<b>Project</b>								
49			01-Jul-04	12-Apr-05	20-Dec-05	28-Mar-06	31-Oct-06	01-Jan-07	31-Dec-07	31-Dec-08
50		Sales	£ -	£ -	£ -	£ -	£ -	£ -	£ 13,500	£ 105,968
51		Cost of Goods Sold (COGS)	£ -	£ -	£ -	£ -	£ -	£ -	£ 6,750	£ 52,984
52		Marketing	£ -	£ -	£ -	£ -	£ -	£ -	£ 33,333	£ 32,333
53		Development Cost	£ 1,401	£ 2,857	£ 4,002	£ 4,002	£ 3,290	£ 11,375	£ -	£ -
54		Project Free Cash Flow before Tax	£ 1,401	£ 2,857	£ 4,002	£ 4,002	£ 3,290	£ 11,375	£ 26,583	£ 20,651
55										
56		Terminal Value	£ 1,000							
57		Project NPV	£ 62,569							
58		<b>Client</b>								
59			01-Jul-04	12-Apr-05	20-Dec-05	28-Mar-06	31-Oct-06	01-Jan-07	31-Dec-07	31-Dec-08
60		Sales	£ -	£ -	£ -	£ -	£ -	£ -	£ 13,500	£ 105,968
61		Cost of Goods Sold	£ -	£ -	£ -	£ -	£ -	£ -	£ 6,750	£ 52,984
62		Marketing	£ -	£ -	£ -	£ -	£ -	£ -	£ 33,333	£ 32,333
63		Development Cost	£ 1,401	£ 2,857	£ 4,002	£ 4,002	£ 3,290	£ 11,375	£ -	£ -
64		Depreciation	£ -	£ -	£ -	£ -	£ -	£ -	£ -	£ -
65		Milestone Payments & Royalties	£ 1,000	£ 2,000	£ 2,000	£ 2,000	£ 2,000	£ 2,000	£ 1,350	£ 10,597
66		Profit before tax	£ 2,401	£ 4,857	£ 6,002	£ 6,002	£ 5,290	£ 13,375	£ 27,933	£ 10,054
67		Taxes	£ -	£ -	£ -	£ -	£ -	£ -	£ -	£ -
68		Profit after taxes	£ 2,401	£ 4,857	£ 6,002	£ 6,002	£ 5,290	£ 13,375	£ 27,933	£ 10,054
69		Free Cash Flow	£ 2,401	£ 4,857	£ 6,002	£ 6,002	£ 5,290	£ 13,375	£ 27,933	£ 10,054
70										
71		Terminal Value	£ 332							
72		Client NPV	£ 39,178							
73		<b>Phytopharm</b>								
74			01-Jul-04	12-Apr-05	20-Dec-05	28-Mar-06	31-Oct-06	01-Jan-07	31-Dec-07	31-Dec-08
75		Milestones	£ 1,000	£ 2,000	£ 2,000	£ 2,000	£ 2,000	£ 2,000	£ -	£ -
76		Royalties	£ -	£ -	£ -	£ -	£ -	£ -	£ 1,350	£ 10,597
77		IP Rights	£ -	£ -	£ -	£ -	£ -	£ -	£ -	£ -
78		Gross Profit	£ 1,000	£ 2,000	£ 2,000	£ 2,000	£ 2,000	£ 2,000	£ 1,350	£ 10,597
79		Taxes	£ -	£ -	£ -	£ -	£ -	£ -	£ -	£ -
80		Free Cash Flow	£ 1,000	£ 2,000	£ 2,000	£ 2,000	£ 2,000	£ 2,000	£ 1,350	£ 10,597
81										
82		Terminal Value	£ 668							
83		Phytopharm NPV	£ 23,391							
84										

Figure 8. The MODEL sheet contains a profit and loss statement for the project and both parties.



## **A discount rate reflecting inherent project risk**

A difficult issue when valuing an R&D project is determining the correct discount rate to be used. As stated above, companies generally use a company-wide WACC, although this may not be appropriate if (the risk of) the project being valued is not typical for the projects in the company. Moreover, the discount rate is an important issue in R&D licensing negotiations, because of its high impact on the project's value. Phytopharm needed an objective approach for determining a discount rate that could be used during its negotiations with potential licensing partners as an anchor point for discussion, in order to counter the licensee's inclination to propose an excessively high discount rate.

Ideally, one should use a discount rate that reflects the systematic, i.e. non-diversifiable, risk of the project being valued. This risk will depend on the risk profile of the project, in terms of variances in the project's returns, on the correlations of those returns with the market returns and on the options embedded in the project. In our valuation model, we use a framework for valuing projects based on explicitly determining the correlation of the project's returns with the market returns. Our methodology is detailed in De Reyck, Degraeve and Vandendorre (2003). When this correlation is known, the present value of the project can be readily determined using the Capital Asset Pricing model (Sharpe, 1965; Lintner, 1965).

## **Milestone payments based on phase risk**

The model is primarily designed for evaluating licensing deals by examining the value of the project and the value of a specified package consisting of milestone payments and royalties. However, Phytopharm's management was also interested in guidelines on the milestone payments, i.e. indications of which size of milestone payments would be "appropriate". One can think of milestone payments as a remuneration for the value created during the preceding phase. If a phase with a low likelihood of technical success is passed successfully, the NPV of the project will increase substantially from then onwards. The milestone payments can be set to reflect this increase. Therefore, we adopted the following approach for providing guidelines on suitable milestone payments. At each milestone, i.e. after each phase, we compute the increase in the project's NPV as a result of successfully passing that phase. A suggested milestone payment is then computed, based on the total value of the milestone package, but allocated according to the value created during each phase (row 41 in Figure 7). In effect, this means that the suggested milestone payment depends on the probability of technical success of each phase. The lower the probability, the higher the milestone payment if the phase is passed successfully. Each proposed milestone payment is then expressed as a percentage of that increase (row 42 in Figure 7). This allows Phytopharm and the licensee to agree upon an appropriate split of the value creation, which results in suggested milestone payments being automatically computed.

## Sensitivity and Simulation Analysis

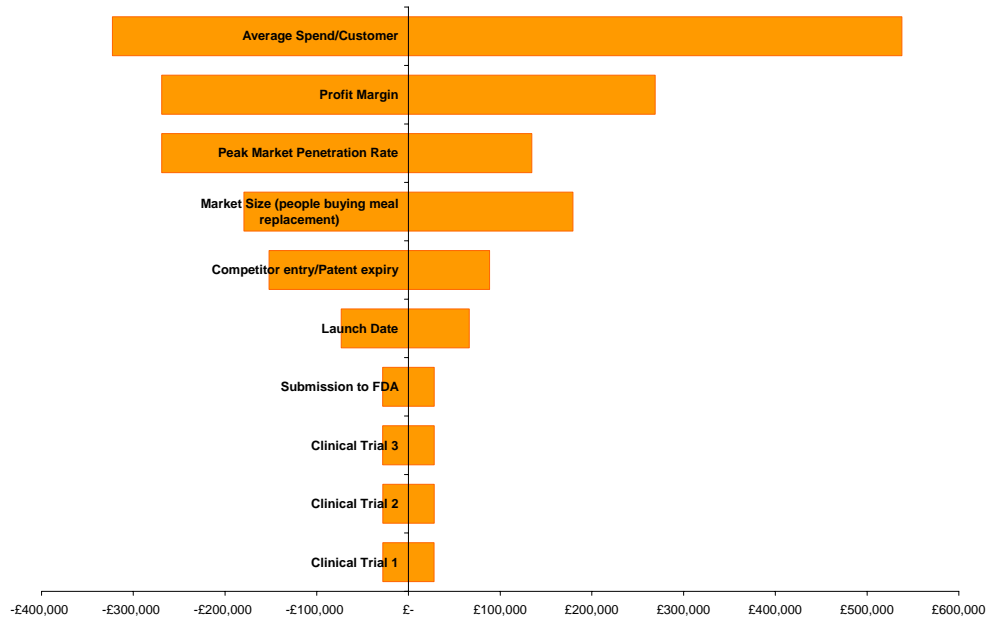
The project's NPV determined above depends on a number of assumptions, including estimated development costs, probabilities of technical success of each project phase, profit margin, launch date, patent expiry, phase durations, and sales forecasts, which in turn depend on the market size, the penetration rate or market share, and the average spend per customer. As we have seen throughout the discussion of the model, the values for these parameters are reached by agreement between the negotiation partners, and are based on expert estimates. This agreement forms the initial stage of the negotiations, on the basis of which the contract terms are discussed. We included a scenario analysis that allowed Phytopharm to explore which parameters had the strongest impact on the project value, in order to decide on which parameters to hold strong and on which to possibly compromise during the negotiations.

As shown in Figure 9, for each parameter in the model, an optimistic and pessimistic value can be entered, next to the base case or most likely value. Using the Data Table functionality in Excel, we then create tables showing how different parameter settings would affect the NPV values. A Tornado chart is created, listing the ten most influential parameters in order of impact on the project NPV. An example, with disguised information, is shown in Figure 10 for the DCO project.

	A	B	C	D
1		Pessimistic	Base Case	Optimistic
2	Launch Date	01-Jan-08	01-Jan-07	01-Jan-06
3	Profit Margin	40%	50%	60%
4	Start Clinical Trial	40%	50%	60%
5	Clinical Trial 1	50%	60%	70%
6	Clinical Trial 2	70%	80%	90%
7	Clinical Trial 3	70%	80%	90%
8	Submission to FDA	70%	80%	90%
9	Agronomy	100%	100%	100%
10	Peak Market Penetration Rate	20%	40%	50%
11	Market Size (people buying meal replacement)	10,000,000	15,000,000	20,000,000
12	Market Size Growth	2.00%	2.00%	4.00%
13	Early adopters in year of launch	0%	5%	10%
14	Average Spend/ Customer	£ 20	£ 45	£ 100
15	Competitor entry/Patent expiry	2010	2018	2020

**Figure 9.** The scenario sheet specifies optimistic and pessimistic values for each of the model's assumptions, enabling a sensitivity analysis of each model parameter.

An essential characteristic of R&D projects is a high degree of uncertainty. In a typical pharmaceutical project, it is highly likely that the product does not make it through all the development phases. This technological risk depends on how innovative the product is and how unfamiliar the technology. There is also the risk that the product, when launched, is not commercially successful. This commercial risk depends on general economic conditions, market size, market share, profit margin and various other factors.

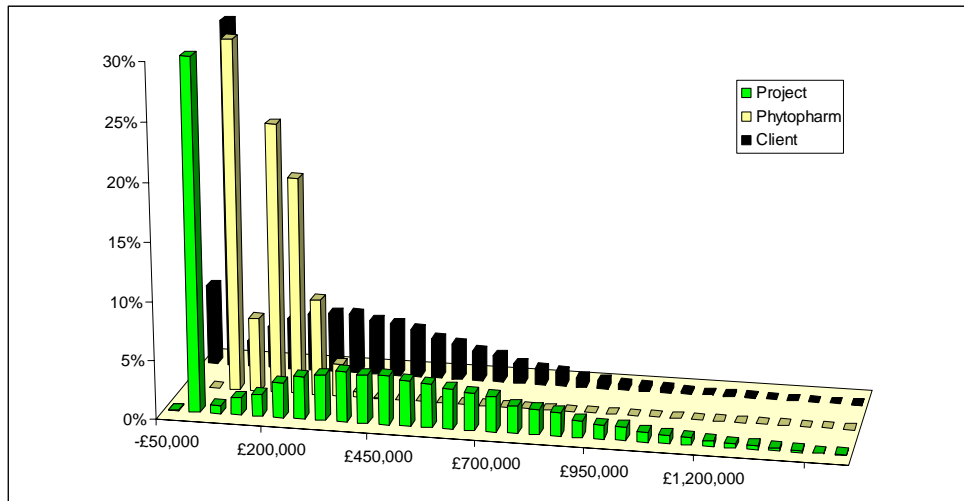


**Figure 10.** A tornado diagram shows the most influential model parameters, sorted according to their impact on the project NPV as their value is varied between its optimistic and pessimistic estimate.

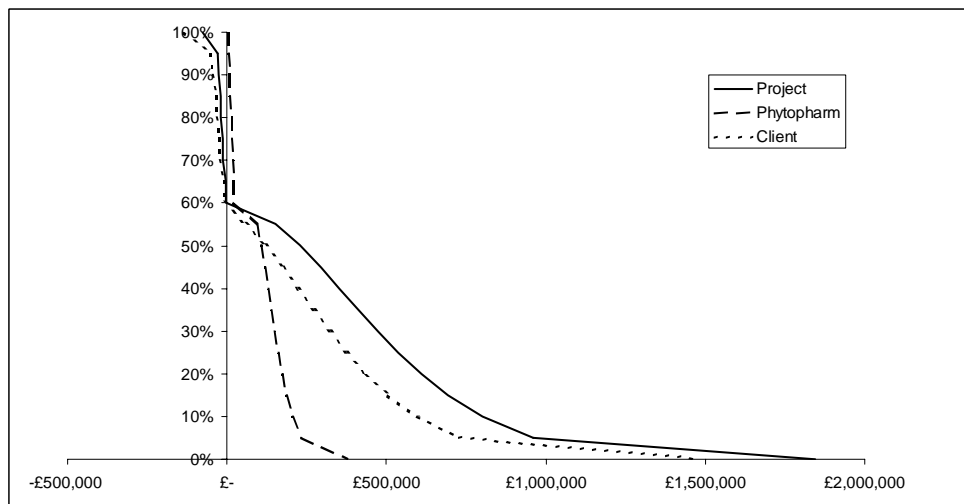
We have included functionalities in our model that allows a Monte Carlo simulation analysis to investigate the technological and commercial risk of an R&D project. The simulation provides an extended sensitivity analysis and a graphical representation of the risk sharing resulting from the contract terms. The simulation results are based on the probabilities of technical success of each of the project phases, and on the ranges on each of the model's parameters specified in the sensitivity analysis section. For the development stage, we use binomial distributions using the probability of technical success of each phase, whereas for the market stage, we use triangular distributions for each parameter, with the mode equal to the specified base case value, and the tail percentiles equal to the specified pessimistic and optimistic values. By taking random samples from the distributions for each parameter, we obtain the possible range of values for the NPV of the project, allowing us to construct a confidence interval. This can be done for the project as a unit of analysis, or separately for Phytopharm's contract and for the licensee's contract.

Simulation results are provided in the model in the form of histograms and cumulative probability distributions for the project's NPV and the NPV for both parties. Figures 11 and 12 show these graphs for the DCO project, obtained using the Excel add-in @Risk. Brealey and Myers (2000, p. 275), among others, warn against using NPV distributions for making investment decisions, as such distributions are difficult to interpret and do not correctly reflect the project's risk when a risk-free discount rate is used to obtain them. Therefore, in our model, the project valuation is still based on NPV calculations using expected cash flows and a risk-adjusted discount rate, and simulation is

merely used as an advanced sensitivity analysis tool. Its purpose is to visualize the risk sharing between Phytopharm and the licensee according to the proposed contract, and to enhance understanding of the impact of the contractual terms on the risk borne by the two parties. It displays the typical structure of an R&D project, with a significant chance of a loss, and a highly uncertain value on the market. The cumulative distribution shows the same pattern, but allows a better comparison of the distributions. Whereas Phytopharm will never incur losses due to the milestone payments, if we ignore the sunk costs of earlier investments, it does not have a large upside potential either, as opposed to the licensee, which benefits from a large upside potential at the expense of the possibility of losses.



**Figure 11.** A histogram shows the range and likelihood of possible NPV values for the project and for both parties, according to the proposed contract terms.



**Figure 12.** A cumulative probability distribution of the NPV shows the likelihood of obtaining a certain NPV for the project and for both parties.

## Negotiations Model

Since the model was primarily designed to be used during licensing negotiations, it was important for Phytopharm to have information on potential trade-offs that could be made, in case some of the terms of the proposed agreement would not be satisfactory for the licensee. If, for instance, the licensee deems that the proposed milestone payments are too high, these can be lowered without affecting Phytopharm's NPV by increasing the royalties appropriately.

In the model, we provide information on how an increase or decrease in milestones or the royalty percentage would affect Phytopharm's NPV. This information is shown in Figure 13 for the DCO product, where the top table contains the milestone and royalties deltas, and the bottom table is a so-called "compensation table", showing by how much one payment has to increase to compensate for another payment's reduction in order to keep the NPV constant.

	A	B	C	D	E	F	G	H
1		<b>Loss per reduction ('000)</b>						
2	Royalties (per % point)	£ 200						
3	Milestones (per \$ million)							
4	Start Clinical Trial	£ 1,000						
5	Clinical Trial 1	£ 461						
6	Clinical Trial 2	£ 257						
7	Clinical Trial 3	£ 200						
8	Submission to FDA	£ 150						
9	Agronomy	£ 118						
10								
11								
12	<b>Compensation Table ('000)</b>					<b>Milestones (per \$1 million decrease)</b>		
13		<b>Royalties (per % decrease)</b>	<b>Start Clinical Trial</b>	<b>Clinical Trial 1</b>	<b>Clinical Trial 2</b>	<b>Clinical Trial 3</b>	<b>Submission to FDA</b>	<b>Agronomy</b>
14	Royalties	-	0.50%	0.23%	0.13%	0.10%	0.08%	0.06%
15	Start Clinical Trial	£ 200	-	£ 461	£ 257	£ 200	£ 150	£ 118
16	Clinical Trial 1	£ 434	£ 2,170	-	£ 558	£ 434	£ 327	£ 257
17	Clinical Trial 2	£ 778	£ 3,887	£ 1,791	-	£ 778	£ 585	£ 460
18	Clinical Trial 3	£ 1,000	£ 4,996	£ 2,303	£ 1,286	-	£ 752	£ 591
19	Submission to FDA	£ 1,330	£ 6,645	£ 3,062	£ 1,710	£ 1,330	-	£ 786
20	Agronomy	£ 1,692	£ 8,455	£ 3,897	£ 2,175	£ 1,692	£ 1,272	-

**Figure 13.** The top section shows the impact of a change in the contract terms on Phytopharm's NPV. The bottom section shows how a decrease in royalties or milestone payments can be compensated by an equivalent increase in milestone payments or royalties, respectively.

The model also includes an analysis based on the concept of the positive bargaining zone (Bazerman, 2001). In a negotiation process, each party typically has a reservation point, namely their opportunity cost or the best alternative to a negotiated agreement (BATNA). In our model, each party can specify a minimum value for the NPV of their part of any proposed contract. The reservation point results in a limit to what each party can ask in order for the deal to go through. Our model includes the possibility to check the bounds, given the licensee's reservation point, on the milestone payments given a certain royalties percentage, or, alternatively, on the royalties, given a milestone payment scheme. This is shown in Figure 14. For instance, the right-hand side of the table shows the reservation points of both parties, namely 20% and 50% of the project's NPV, and below, given the specified milestones of a total value of £3,374,000, the range on the royalty percentage that would

yield NPV values for both parties at or above their reservation point. In this case, the royalty percentage could be anywhere between 4.57% and 13.94%. The left side of the table yields similar results, but in terms of milestones payment ranges for specified royalties.

	A	B	C	D
22	<b>Break-even Analysis - Milestone Payments</b>	<b>(% of NPV)</b>	<b>Break-even Analysis - Royalties</b>	<b>(% of NPV)</b>
23	Phytopharm	20%	Phytopharm	20%
24	Client	50%	Client	50%
25				
26				
27	<b>Target Royalties</b>	<b>10%</b>	<b>Target Milestones</b>	<b>£ 3,374</b>
28				
29	<b>Lower Limit on Milestone NPV</b>	<b>£ -</b>	<b>Lower Limit on royalties</b>	<b>4.57%</b>
30	<b>Upper Limit on Milestone NPV</b>	<b>£ 11,268</b>	<b>Upper Limit on royalties</b>	<b>13.94%</b>
31	<b>Minimum Percentage of Value Created at Milestone</b>	<b>0%</b>		
32	<b>Maximum Percentage of Value Created at Milestone</b>	<b>18%</b>		
33				
34	<b>Present Distribution</b>		<b>Present Distribution</b>	
35	Phytopharm	37%	Phytopharm	37%
36	Client	63%	Client	63%
37	Taxes	0%	Taxes	0%
38	Third Party (IP Rights)	0%	Third Party (IP Rights)	0%
39				

**Figure 14.** This table displays the “bargaining zone” for royalties and milestone payments. For a specified royalty percentage or milestone payment, the table shows the possible range on milestones or royalties satisfying the reservation points.

## Model Use

### Internal Model Use

Given Phytopharm’s strategic focus on licensing, this project was of major importance to the company. Therefore it had top management’s complete support and the resulting model was widely circulated amongst its employees. This resulted in feedback from different perspectives, ensuring the model’s comprehensiveness. The main user of the model was the CFO, Dr Wang Chong. The other executive directors also requested to be instructed on the working of the model. The development of the model thus became very interactive, with important input from end-users. Some features have been added explicitly at their request, such as flexibility in the number of phases or a suggested milestone based on the project’s risk resolution profile. We have also included IRR calculations and Payback Period information at Phytopharm’s request. Though we are fully aware of the disadvantages of these measures in decision making, Phytopharm felt that the negotiation partner would like to know those values as they are commonly used in practice. The wide circulation of the model also assisted the transparency and robustness of the model. Also, some features in the model were designed for internal use only and could be hidden from the negotiation partner if required, such as information on Phytopharm’s obligations to third parties or the tornado diagram, which highlights the uncertainties in the model that have the highest impact on the projects’ NPV estimate.

## External Model Use

Phytopharm used the model during its licensing negotiations for the DCO product between June and December 2004. In December 2004, the product was licensed to Unilever, a multinational food company (see press release in Figure 15). We had initially offered our assistance in presenting and running the model at the negotiation meetings with short-listed potential collaboration partners. However, using an 'interpreter' makes negotiations more difficult and Phytopharm felt confident in using and defending the model during the negotiations. From Phytopharm's comments, we gathered that the negotiation partners were surprised by the sophistication of the model.

**Phytopharm and Unilever enter into a License and Joint Development**

*Agreement includes provisions for substantial milestone payments and royalties*

Phytopharm plc (LSE: PYM; NASDAQ: PHYOF) announced today that it has granted an exclusive global license to its Hoodia gordonii extract to Unilever plc, the global consumer products company and owner of a number of the world's leading brands.

As part of the agreement, Unilever will commit to initial payments totaling approximately £6.5 million (\$12.5 million) out of a potential total of £21 million (\$40 million) in payments to Phytopharm. In addition Phytopharm will receive an undisclosed royalty on sales of all products containing the extract.

The extract of Hoodia gordonii, a South African plant, was licensed exclusively by Phytopharm from the South African Council for Scientific and Industrial Research (CSIR) in 1997. Phytopharm has been actively developing the extract for incorporation into weight loss products.

Unilever and Phytopharm will collaborate on a five-stage research and development program of safety and efficacy studies with a view to bringing new products to market. Unilever will also manage a separate agronomy program and will support the international patent program for the products.

Obesity has reached epidemic proportions globally, with more than 1 billion adults overweight - at least 300 million of them clinically obese - and is a major contributor to the global burden of chronic disease and disability (Source: World Health Organization).

Commenting on today's announcement, Dr. Richard Dixey, Chief Executive Officer of Phytopharm, said: "We are delighted to enter into this agreement with the global leader in weight management products. Our partnership with Unilever supports the development of this product with milestones and a fully funded program and we look forward to generating royalty income from our partner's globally recognized brands."

**Figure 15.** On 15 December 2004, a press release was issued to announce the licensing deal.

The main advantage of the model, according to Phytopharm, was that it enabled the negotiations team to make a robust case for providing credible estimates of the product's value. Valuing a product in early development for licensing negotiations can be a major challenge, as the NPV can be discounted close to zero using a standard DCF/NPV model when the product's launch is many years

away. Typically during such negotiations, the different parties disagree on crucial parameters that influence a product's value, such as the sales forecasts, development costs, margins, likelihood of success, etc., as well as the appropriate discount rate to be used. Our model allowed the negotiations teams to visualize the effect of these different assumptions, and to determine which of these factors had a significant impact on value, and which did not. This allowed a more focused discussion on the important issues. In particular, the model was helpful to discuss and finally determine the PTS and the sales estimates. The model was also useful for visualizing the structure of the project, including the different clinical trials and review procedures. Although pharmaceutical companies are used to operating in this environment, food companies typically deal with more straightforward product development processes, and are sometimes apprehensive to take on risky projects like the DCO project. The model provided a clear overview of all the phases and risks involved, and therefore enabled Phytopharm to propose a deal that would otherwise be alien to most players in the food and consumer goods industries. The visualization provided by the model, for instance in the form of probability distributions, was a useful tool to show the risk sharing element in the contract. The graphs clearly showed different risk profiles for the different partners, with higher risks compensated with higher potential upsides. This allowed Phytopharm to convince their potential licensing partners of the merit of the product. Currently, Phytopharm is planning to deploy the model for its entire project portfolio.

## **Conclusions**

In this paper, we describe an R&D project valuation model developed for Phytopharm plc, a UK biotechnology company, to be used during licensing negotiations. Using Decision Analysis and Monte Carlo Simulation, we determine the Net Present Value of an R&D project, and determine the magnitude of the risks involved, both technical and commercial. The model is currently being used by Phytopharm to develop contract proposals consisting of milestone payments and royalties on sales, based on an agreed-upon equitable split of the project value between the two parties. The model also generates useful information in the form of break-even analyses, trade-offs and bargaining zones. Between June and December 2004, Phytopharm used the model during its licensing negotiations for a novel product for the dietary control of obesity, which resulted in the product being licensed to Unilever, a multinational food and consumer goods company.

Phytopharm is currently planning to deploy the model for its entire project portfolio. Even though Phytopharm only develops products based on plant extracts with strong anecdotal evidence of clinical benefit, hence theoretically improving the probability of technical success of its projects, it still carries substantial technical risk. Whereas the major pharmaceutical companies can diversify the technical



risk of their portfolio through the number of projects involved, smaller pharmaceutical players bear a substantial amount of risk due to their comparatively small portfolios; Phytopharm's portfolio contains approximately 10 projects. For smaller companies, losing a project, failing to license a project or getting a bad deal on a project might be life threatening, emphasizing the importance and the need for quality project valuation tools.

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