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Dealing with uncertainties in the biotechnology industry: The use of real options reasoning

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Abstract Managers of biotechnology companies face great technological and market risks in making investment decisions. Traditional investment decision tools such as the discounted cash flow (DCF) approaches are often deemed insufficient in the face of the highly uncertain environment surrounding biotechnology projects. More recently, there is an increasing interest in real options approaches, which, in contrast to DCF, explicitly takes into account the managerial flexibility to respond to changing internal and external conditions during the course of the project. It is this flexibility that makes real options reasoning not only perceived to be superior for evaluating projects, but also for developing value-enhancing strategies. However, there is considerable confusion about when the real options approach might be applicable in practice, be it in a formal or an informal way. Based on insights derived from interviews with European biotechnology investors and managers, this study provides an overview of the potential benefits and limitations real options thinking has on evaluating and managing risky projects, particularly with respect to biotechnology companies.

Keywords: real options, biotechnology industry, project evaluation, discounted cash flow, investment uncertainties

Introduction

Most companies dealing with emerging technologies face great technological and market uncertainties. This is especially so in the case of the biotechnology industry, where the development of new products involves both *market risks*, which affect all companies in the industry (eg the size and scope of the market, regulatory issues, intellectual property rights (IPR) regimes, competition through generic drugs), and *private risks*, which are more specific to a company and its projects (eg technical

feasibility, approval failure, lack of financial and organisational resources).

Consequently, to reduce the probability of making investment mistakes in the light of the extensive risks faced, managers have to evaluate potential projects as realistically as possible before making major commitments to develop them. In addition, they have to position their firms to benefit from uncertainty. In such situations, strategic planning clearly needs finance and vice versa. However, managers are often baffled by the question of how to include uncertain future outcomes and potential strategic

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responses in the analysis of prospective capital investment projects. ⁴

In this context, several techniques have been used to take into account the potential impact of uncertainties on project outcomes, most notably the discounted cash flow (DCF) methods. However, these traditional investment decision tools are often deemed insufficient in highly uncertain environment surrounding biotechnology projects. More recently, there is an increasing interest in real options approaches, which, in contrast to DCF, explicitly take into account the managerial flexibility to respond to changing internal and external conditions during the course of the project. However, there is still much ongoing discussion about when the real options approach is applicable in practice.

Our interviews with European biotechnology investors and managers revealed an adverse attitude towards risk and an admitted lack of capability to deal properly with the uncertainties inherent in most investment opportunities. In our interviews, we had presented managers with two investment options of early stage drug-development projects to our interviewees. One was likely to be scientifically feasible, promised a higher chance of generating positive cash flows, but had only a very limited chance of becoming a real blockbuster drug (eg a new anti-'flu vaccine). The other was based on the same platform technology, but was highly uncertain with respect to both its scientific success and cash inflows. However, should it succeed, it would offer a huge potential to enter a market with almost no competition (eg an anti-HIV vaccine).

Given these options, with figures for each project's forecasted cash flows and probabilities, the majority of our interviewees decided to undertake the former project despite its limited potential. Most of the interviewees relied on the DCF approaches in making their decision, using higher discount rates for the latter project to take into account its greater level of uncertainty.

However, one manager suggested not committing the total amount of available

funds into one project but investing it stepwise into both projects. With new information available from further R&D results, subsequent investments could then be directed accordingly. In this way, it would be possible to defer the final commitment to a point in time when there is more certainty about the likely outcome of both projects, ie the time when a decision as to whether to continue or abandon one or both projects can be made. Though there is a chance that the initial investment in at least one of the projects might be lost, the risk would be small compared to the potential gains.

When asked about the rationale of his argument, this manager said that it is intuitively unwise to dismiss the promising, albeit uncertain, second project because of the exceedingly high discount rates applied. However, although he was confident, he was unable to provide any formal explanation or hard figures to justify his intuition.

Nevertheless, this manager has unconsciously grasped the main idea of real options reasoning – when there is uncertainty, one might continue to invest as long as one has the flexibility to defer, abandon or commit to a project as further information becomes available. Hence, the value of the project is not linked just to the outcome itself, but also to uncertainty and flexibility.

Though we have observed the intuitive use of real options thinking, there is still considerable confusion about when the real options might be applicable in practice. This paper therefore aims through an overview of the potential benefits and limitations of the naive DCF, advanced DCF and real options methods, to explain how real options reasoning can help – beyond valuation aspects – to develop value-enhancing strategies.

Traditional methods for decision making under uncertainty

Naive DCF method

DCF methods, which emerged in the 1970s, remain the most popular tool in practice for

valuing projects. The naive, or static, DCF method evaluates the net present value (NPV) of a project based on a series of (riskadjusted) cash flows stretching into the future. It assumes a static investment scenario, with clearly defined decision path and associated outcome; and the decision rule is that the firm should invest in the project if NPV is positive and not invest if it is negative.

However, the naive DCF method has many drawbacks when applied to the evaluation of high-technology projects, such as in the biotechnology industry. Most firms using this approach recognise that they face major uncertainties about the future, yet their strategic investment decisions are primarily based on a single projection of future events.4 Cash flows from hightechnology projects are highly uncertain, suggesting that the NPV derived is likely to be based on several assumptions, such as development success or competitors' actions. To compensate for this, higher discount rates are usually used. However, this poses two problems. First, it is difficult to reach a consensus on the appropriate discount rate to use. Second, the high discount rate used often leads to very low or even negative NPV, resulting in a bias against investments in such projects. Furthermore, this method is also criticised for incorporating only two relatively static levers of value creation - cash inflows and cash outflows - and ignores the dynamic nature of most decisions and manager's flexibility to alter future decisions.

New technologies, product ideas or patents present opportunities, which may or may not be exploited now. Fully committing oneself to new ideas early on (if NPV > 0) might be as flawed as fully omitting them (if NPV < 0). Rather, it is more attractive to possess the principal rights to these opportunities and have the managerial flexibility to alter investment decisions until more information is revealed. Clearly, the naive DCF method fails to recognise the value of the options embedded in unpredictable future developments in most emerging technology investments.

Our interviews also suggest that this is a

common problem with respect to the use of the naive DCF method – most of the interviewees were aware that long-term cash flow forecasts and NPVs were questionable and easily manipulated. Many also admitted that the potential opportunities inherent in many projects were not realistically reflected by this method.

Advanced DCF method

To overcome the limitations of the naive DCF method, more advanced and dynamic DCF methods have been developed incorporating decision analysis that reflects the anticipated risks and values (utility function) of the decision-maker. Instead of assuming a single predetermined and static scenario, this approach lays out all possible decision paths, along with their associated probability estimates and outcomes in a hierarchical tree structure. The value of an investment is then calculated by folding back the branches of the decision tree to determine its expected NPV. Monte Carlo simulations and sensitivity analyses are commonly used to help assess the effects of different assumptions and scenarios represented in the decision tree.

The advanced DCF method is clearly superior to the naive DCF method, as it incorporates managerial experience more realistically and allows for the simultaneous consideration of several potential outcomes. This method, however, also has its limitations. As in the naive DCF method, the expected values and probabilities are based on the information available at the time of project assessment and the manager's estimation. In addition, a manager's subjective utility function may also differ from how the market values a company based on its project's outcome. Moreover, probability estimates are usually reflected in a single discount rate – although, in practice, different project phases often have different risks that warrant different discount rates. Since the computed investment valuations are very sensitive to subjective estimates of probability and risk, great care must be taken when developing realistic model

inputs. Finally, most investments have multiple decision points and to include all likely internal and external factors that might have an impact on a project's outcome can present both structuring and computing challenges. In general, owing to the complex nature of this approach, it is not surprising to find that only a small number of our interviewees use it.

Real options method

A comparison of the real options method with DCF methods

In view of the shortcomings of the DCF approaches, many experts expect them to be replaced by the real options method as the dominant investment decision tool within the next five years. Some practitioners, such as Julie Lewent, the Chief Financial Officer of Merck, even suggest that all kinds of business decisions are options that can be dealt with using the real options approach.

Before we further explain the concept and use of the real options method and how it contrasts from the DCF methods, it is necessary to recall some knowledge of the financial option pricing methods. A financial option confers the right - but not the obligation - to buy (call) or sell (put) a traded asset (eg stock) at a fixed exercise price on a fixed exercise date (European call/put) or within a fixed period (American call/put). The option derives its value from this right. The most commonly used formula for determining the value of a simple financial call option was developed by Black and Scholes' and modified by Merton:8

$$V = Se^{-\delta t}[N(d_1)] - Xe^{-rt}[N(d_2)]$$

where N(d) is the cumulative normal distribution function;

$$d_1 = {\ln(S/X) + (r - \sigma + \sigma^2/2)t}/\sigma\sqrt{t}$$

and $d_2 = d_1 - \sigma\sqrt{t}$.

For definition of terms see Table 1.

Broadly speaking, the value of an option is obtained from the uncertainty associated with an investment opportunity – expressed as the volatility of its potential returns. Until

the option's expiry date (if there is any), the option holder has the opportunity to continuously reassess its potential payoff. If the value of the underlying asset goes up by more than the price of the option, the option holder should exercise it; otherwise, he will not exercise. Hence, the option holder preserves the ability to benefit from a great upside potential while limiting the downside risks to the cost of buying the option. This asymmetric distribution of returns is an essential options characteristic that distinguishes it from DCF approaches, and the issue is no longer just on whether the NPV is positive or not.

Another important difference between the DCF and options methods is that the latter take the financial market perspective when evaluating a project. This involves using a 'replicating portfolio', created by combining the underlying asset with risk-free borrowing. This replicating portfolio has the same market-priced cash flows (risk profiles) as the asset being valued and is perfectly correlated with it. According to the principles of arbitrage, the value of the replicating portfolio therefore must be equal to the value of the option (law of one price). This is a convenient way of using existing information about how the market prices a particular risk profile. With this, the options approach avoids - in contrast to DCF methods - the need to estimate probabilities, risk-adjusted discount rates or utility functions. In this context, taking a risk-neutral approach to valuing options is another distinct aspect of the options approach – it used risk-neutral probabilities derived from the price ranges of the replicating portfolio. This is analogous to discounting certainty-equivalent cash flows at the risk-free rate, rather than employing expected cash flows at a risk-adjusted rate. However, it is important to note that although probabilities and measures of risk aversion are not used directly, the market value of the risks of the option under consideration is included through the market value of the underlying asset.4

Proponents of *real options reasoning* argue that the thinking behind financial options may be translated to opportunities in real (ie

non-financial) markets, such as in real investment opportunities.^{5,10,11} Many corporate investment projects bear a strong resemblance to a financial call option in that they confer on its holder the option to invest, wait or divest in response to new information. Thus, the real options approach is said to be particularly appropriate for evaluating investments in high-technology projects, 12 which are characterised by highly asymmetrical payoffs, highly uncertain future revenues and costs, relatively high commercialisation costs as compared to initial investments, progressive nature of decisions and long time horizons.

The analogies of financial and real options are even more apparent when one compares the input variables of the Black–Scholes formula with the features of a real investment project as listed in Table 1.

However, although the Black–Scholes formula is useful for illustrating the analogies of financial and real options, it is rarely used for the evaluation of the latter. This is due to its complexity (which reflects complex continuous stock price movements, called 'Brownian motion') and restrictive underlying assumptions. It is therefore often perceived to be applicable primarily to simple American call options, but not common and complex types of real options.

For this purpose, Cox et al. 13 suggested a simplified time-discrete binomial lattice option-pricing model that requires only elementary maths (and contains the Black–Scholes formula as a special limiting case). As this approach is more commonly applied for evaluating real options, we briefly discuss in the following. Referring back to the investment choices given to our

interviewees as outlined in our introduction, one can view the investment opportunity as a sequential compound option – an option (to defer full commitment and conduct further R&D to gather information on both projects' potential) on another option (to expand commitment to the more promising project) as shown in Figure 1.

A characteristic of sequential compound options is tht a subsequent option is only created when the preceding one is exercised. For evaluating such options, the binomial lattice model assumes that the asset prices, in any discrete period, can move up or down. To calculate the overall value of a compound option with this model, one folds back the tree structure and determines the option value (gross value of a project) at each decision node. Using the option pricing approach often reveals that the value of an uncertain investment opportunity that allows for flexibility is greater than that calculated by DCF methods. A short description of the evaluation procedure based on the binomial lattice model is given in Appendix A.

Summarising what was described so far, the main differences between the naive DCF, the advanced DCF and the real options methods can be sketched out as shown in Table 2.

While most experts today agree that the naive DCF method is insufficient in most cases, there has been some debate on which of the 'dynamic' approaches, ie the advanced DCF or real options method, is superior. Some argue that when both methods reflect a similar market perspective and are applied correctly, they might produce similar results. However, in most cases, they often yield different outcomes.

 Table 1 The real option equivalents of the Black-Scholes financial option input variables

Variable	Financial option	Real options approach to investment opportunity
S X ₂ σ r t δ	Stock price Exercise price Volatility Risk-free rate Time to expiry Dividends	Present value of the expected cash inflows from project Present value of the expenditures needed to accomplish project Uncertainty of the expected cash flows from the project Time value of money Period over which the investment opportunity is available Cost to preserve option – value that depreciates over time

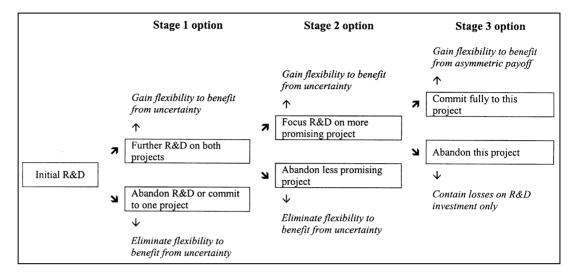


Fig. 1 Decision tree of a sequential compound option

Table 2 A comparison of the real option method with the naive and advanced DCF methods

	Naive DCF	Advanced DCF	Option pricing
Decision path Primary value driver	Determined initially Tangibles (assets in place)	Determined initially Tangibles (assets in place) & intangibles (learning)	Defined continuously Tangibles & intangibles (learning)
Orientation Value of information	Internal/subjective Ignored	Internal/subjective Dependent on initial assessment	Market-based/objective Continuously increasing over option's lifetime
Value of flexibility	Ignored	Dependent on initial assessment	Prerequisite for option's value
Value of uncertainty	Often mistreated by high discount rates	Dependent on initial assessment	Prerequisite for option's value
Computability Correctness	Simple Low	Complex High	Moderate High

The choice, therefore, depends largely on whether replicating assets can be identified and valued in the market, and on the confidence with which managers are able to estimate project payoffs. The real options approach seems to have the greatest value in situations when there is uncertainty, when managers have the flexibility to respond to it, and when the NPV is close to zero – that the additional value of flexibility makes a big difference.⁵

Although these characteristics seem to be common among biotechnology projects, the real options pricing method is currently being applied primarily to the oil and electricity industry. This may be due to several reasons. Our interviews suggest that

the key reason is the lack of expertise. Most of the interviewees are not proficient in this method, and consequently never use it in a formal way. Even for those who know the fundamentals, the method is considered to be too complicated as compared to the naive DCF methods. Other reasons identified are mismatches between a project's characteristics and the parameters of an option pricing model, ¹⁴ the common lack of traded underlying assets to create a replicating portfolio, and the predominance of private risks compared with market priced risks.² On these grounds, the formal use of real options method might be of limited use to evaluate investment opportunities in the biotechnology industry.

If accurately applied, the advanced DCF method might be more helpful. Nevertheless, the real options method does offer some other strategic investment guidelines that are of use to the biotechnology industry. This will be discussed in the next section.

The strategic use of real options reasoning

Though the formal application of the real options method is of limited user, experts increasingly acknowledge that to benefit from real options reasoning, it is unnecessary to apply it formally. They argue that the value of the real options approach lies not in the output of the Black–Scholes or other formulas, and that determining the exact value of a real option is not critical. Rather, the greatest benefit of real options reasoning is *thinking strategically* – as a basis for actively increasing the value of option-like projects. ¹⁶

The accelerating pace of the biotechnology industry is shrinking the window with which any given strategy, however well thought out, remains viable. Therefore, strategy making should be a dynamic process, comprising a series of flexible decisions optimised as circumstances evolve. In this context, using a real options approach indeed might be of considerable help to develop value-enhancing strategies in an uncertain world.

Implementation of real options reasoning

To implement real options reasoning, Hamilton¹² suggests that the real options approach might be thought of as a cyclical process (Figure 2).

Adopt real options perspective to recognise shadow options

Real options arise in most technology investments but recognising them is often difficult – particularly for those managers who are used to adopting the DCF methods. As a result, potential opportunities may not be recognised as real options without a fundamental shift in managerial mindset. Hence, the first crucial step of the real options approach lies in identifying the existing – but often concealed – 'shadow' options inherent in most projects.

Create new options by structuring decisions to increase flexibility

Some real options might not arise naturally, but require systematic structuring of decisions. The real options perspective helps to *systematically* identify the key variables that determine an option's value as provided, eg using the Black–Scholes formula. ¹⁶ Even though this formula might not be applicable for the formal pricing of real options for most of the time, it is nevertheless useful for identifying the keylevers for increasing their values strategically.

Table 3 summarises the effects of increases in the variables of the Black–Scholes formula on the value of a project and some examples for the corresponding managerial actions.

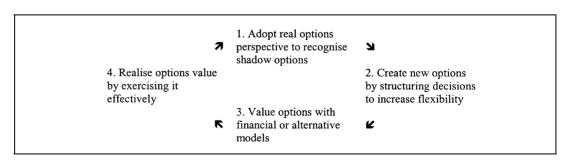


Fig. 2 Implementation process of real options reasoning

Table 3 Effects of increases in the real option equivalents of Black-Scholes financial option input variables on the value of a project and examples of corresponding managerial actions

Variable	Effect on (real) options value	Examples for managerial actions
S Stock price, ie PV of future cash inflows	Positive	 Grow revenues and cash inflows: Increase revenues by raising price and/or producing more products (where possible) Write and trade real options contracts on the outcome of option-like projects (see Appendix B.1) 18 Create a put option on a competitor (see Appendix B.2) 18
X Exercise price, ie PV of future expenditures	Negative	Reduce present value of fixed costs & cash outflows: • Leverage economies of learning, scale and scope • Plan project into stages • Invest in additional R&D projects related to core activities • Outsource peripheral tasks
σ^2 Volatility of returns, ie uncertainty of project value	Positive	Amplify uncertainty of cash flows: • Conduct research over a wider scope to increase the level of uncertainty and hence the chance to make new discoveries
r Risk-free rate, ie time value of money	Positive	Monitor closely.
t Time to expiration, ie time decision can be deferred	Positive	 Expand duration of option: Delay project as far as possible to filter in new information Enhance length of patent protection for products/ processes by legal actions Capture important assets such as patented technologies and leading experts or establish alliances
δ Dividends, ie opportunity costs to preserve option	Negative	Diminish value lost by waiting: • Discourage competitors by publicly signalling ability to exercise option

Value options with financial or alternative models

Once options are recognised and/or created, it is desirable to assess their values as precisely as possible with formal option pricing methods – as quantitative techniques offer important and valuable support for the managerial judgment on which all significant decisions must ultimately rest. Yet, as mentioned above, it is questionable as to whether this approach is appropriate for evaluating biotechnology projects.

Nevertheless, commitments to new product developments are usually made in anticipation of several potential benefits: (1) the financial returns generated by future cash flows from successful commercialisation of the products; (2) advantageous strategic positioning that provides future opportunities for strategic initiatives or building new distinctive competencies; and (3) the new knowledge

created by investments in emerging technologies can be of significant value in guiding future investments in related products. It must be noted that quantitative assessment is particularly difficult with respect to strategic positioning and knowledge generation. Hence, a certain degree of judgment is always involved in investment decisions.

A number of companies have placed primary reliance on managerial judgment in selected strategic investment situations. ¹² This is to ensure that major projects with significant upside potential due to embedded real options – be it in the form of financial returns, strategic positioning or knowledge – are not inappropriately undervalued and perhaps even rejected because of the inadequacies of financial evaluation methods.

However, believing that a precise calculation of options value is not meaningful does not necessarily mean that we should fall back on relying on intuition totally. 19 This approach might be used, for instance, in the form of a 'threshold' assessment, which does not attempt to calculate the values of future flexibility directly. Instead, managers can first compute the value of the investment using conventional DCF methods, recognising that the value of embedded options may be ignored or substantially understated. To the extent that the results fall short of an acceptable threshold level, the value of both strategic positioning and knowledge creation options (often without hard figures) are then considered in judging whether the value of future flexibility is sufficient to compensate for this shortfall. By framing the problem in this manner, the focus shifts from attempting to compute an absolute value for the real options embedded in the decision to the issue of whether the value of the options is enough to justify the investment. This requires a careful and rigorous examination of the embedded options and some judgments about their values relative to the decision threshold the minimum acceptable level of returns required to initiate an investment project under uncertainty.

Realise options value by exercising it effectively

Finally, real options and their value are not static; real options focus on future values, which by definition, do not exist at the time the options are assessed. Changing market conditions, competitor actions, unexpected research outcomes, shifting strategic priorities and a host of other internal and external factors may affect subsequent decisions and the value of embedded options over time. The added value of flexibility captured by real options measures, in general, decreases over time.¹⁵ In fact, to achieve the full value of real options requires the continuous evaluation of alternatives and expectations. This, in turn, requires an active management system where managers pay careful attention to the nature and timing of their investment activities. Managers must regularly monitor

and update information on project progress, test and update key assumptions when certain project milestones are achieved, and exercise options timely. It is evident that these activities also require considerable changes in organisational structures, processes and corporate culture. However, these changes will ultimately provide advantages to those companies that have developed the capability to create, evaluate and implement real options.¹²

Conclusion

The central issue of any investment decision-making is how to cope with uncertainty. To manage emerging technologies and capture their full values successfully, managers need to go beyond traditional investment decision methods and incorporate real options reasoning in their evaluation.

In industries where projects are characterised by huge technological and market uncertainties, such as in the biotechnology industry, real options reasoning can have broad applications as a management tool. They will enhance managers' thinking and value creation. Though real options reasoning is sometimes criticised for not being more than common sense and intuitively being applied by many managers, we argue that the fact that it is already applied unconsciously does not make it less valuable. Moreover, we are convinced that a more structured and transparent approach to option-like projects is likely to improve decision making in many cases.

Though the real options method does not eliminate or even reduce the uncertainties inherent in emerging technology projects, it explicitly pay attention to such uncertainties. Hence, its greatest benefit comes from forcing managers to confront the uncertainty issue head-on and formalise the whole range of strategic decisions that might be considered over time. The resulting insights can be valuable even if the estimate of an option's value is not perfect.²⁰

In summary, this paper provides four key

lessons about real options thinking that are useful for biotechnology managers:

- recognising the real options embedded in most projects is fundamental;
- determining the exact value of real options is not necessarily critical;
- understanding the drivers of the valuation and their relative values is critical; and
- when there is flexibility to react on future information, uncertainty is valuable!

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Appendix A

To calculate the value of the option at each decision node, the binomial lattice method uses the following formula:

$$V = [pV_{\rm u} + (1-p)V_{\rm d}]/(1+r)$$
 where $p = [(1+r)R - R_{\rm d}]/(R_{\rm u} - R_{\rm d})$.
$$V_{\rm u} = \text{upside value}$$

$$V_{\rm d} = \text{downside value}$$

At each decision node, the gross value of the project (eg V) at the beginning of that period can be determined as a 'certainty-equivalent' value by the price movements of the (perfectly correlated) replicating portfolio (eg $R_{\rm u}$ and $R_{\rm d}$) – using risk-neutral probabilities p (instead of the actual probabilities that would be used in a DCF approach) and discounting at the risk-free rate (r).

This gross value of the project, in turn, provides the investor with the necessary information to help decide whether he or she should invest further in, defer or abandon the next option, ie the next stage of the project. Assume, for instance, the investor has to invest an amount I_0 at the first decision node. Then, the project's net value (N) at the second decision node will

either be $N_{1\mathrm{u}} = \max(V_{1\mathrm{u}} - I_0, 0)$ or $N_{1\mathrm{d}} = \max(V_{1\mathrm{d}} - I_0, 0)$; and the project's total initial value will be: $N_0 = [pN_{1\mathrm{u}} + (1-p)N_{1\mathrm{d}}]/(1+r)$. The value of the option is then calculated as the net value of the project less the static NPV.

Appendix B

1. Write and trade real options contracts on the outcome of option-like projects: A (cash-constrained) biotechnology company can create value by writing and trading option contracts on the outcome of its exploration projects, for instance, to alliance partners in exchange for (milestone or royalty) payments. If the project is successful, the rights (eg on sales and marketing) are

passed to the trading partner; otherwise, there are no obligations.

2. Create a put option on a competitor: It is often the case that the potential product of a biotechnology company could tap into an existing market controlled by a competitor. The more directly the potential product impacts the competitor's product, the more accurately its success will be reflected in the downward movement in the rival's share price. Hence, it can purchase some rival firm stocks before announcing its own development programme. In other words, it can create a put option on the competitor. If the programme succeeds, the rival's shares will fall and the put can be realised. This will capture additional values on top of what is reaped through the company's own development success and/or the value increase of its own call option.

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