

# Application of real options analysis for pharmaceutical R&D project valuation—Empirical results from a survey

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## Abstract

Real options analysis was often recommended as an emerging valuation technique for high-risk investment projects. Former inter-sectoral surveys have drawn an ambivalent picture of real options usage in general. In addition, there is a lack of sector-specific investigations. In the following article the results of an in-depth analysis of collected empirical data regarding the application of this new tool in the pharmaceutical sector is presented by capturing the internal view from the pharmaceutical companies themselves and the external view from the health care departments of financial service firms. R&D stage specific modi of application, reasons for reluctance in the employment of real options and their assumed future prospects are elucidated.

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**Keywords:** Real options; Pharmaceutical industry; R&D; Investment analysis; Project valuation

## 1. Introduction

“The value of R&D is almost all option value” postulated Myers in 1984 who firstly recognized the analogy between financial options and real world investments. For this relationship, he coined the expression *real option*. This term describes the cognition that, based on the resemblance mentioned above (R&D) investments can be valued similar to financial options. The scientific basis for this task is provided by the research of Black/Scholes and Merton who were awarded the Nobel prize in 1997. Real options account for management flexibility which delivers a significant value contribution in the presence of uncertainty. Therefore, real options

analysis (ROA) was recommended several times to be more adequate than traditional Net Present Value (NPV) for judging R&D projects (e.g. Newton et al., 2004). In addition, following a real option’s perspective on R&D projects in R&D-intensive companies has a positive impact on both their R&D performance and their financial performance (Kumaraswamy, 1998).

These notable statements raise the question of the actual level of usage of ROA for valuation tasks inside the affected companies. However, due to the exclusive inter-sectoral nature of the surveys conducted so far, there is no exact picture available that tracks the concrete situation in one particular real option branch.

This paper aims at investigating the application of real options analysis in the pharmaceutical industry. Thereby, R&D projects as well as the assessment of whole companies are focused. The study considers every R&D stage and the different project valuation methods applied there. The current and the expected usage of real options analysis are determined. The data collection is performed

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using a survey based on a written questionnaire. The main international pharmaceutical companies as well as the health care departments of financial service companies have been addressed.

The current article presents the first detailed empirical data of real options analysis for pharmaceutical R&D and comprises the following sections: we begin with a short introduction on the current situation of the pharmaceutical industry and the particular features of the R&D process in this sector (Section 2). An overview of real options analysis is given in Section 3. The results from other surveys regarding real options usage are presented in Section 4. Subsequently, the concept of the actual survey is explicated (Section 5), accompanied by the respective outcomes (Section 6). Finally, a critical discussion is undertaken in Section 7.

## 2. Challenges of the pharmaceutical industry and the research and development process

During the last decade, the pharmaceutical companies delivered double digits growth rates on average. To sustain this path, at least four new drug launches (with annual sales of \$ 350 million) per year are required for every of the large pharmaceutical companies (Bolten and DeGregorio, 2002). However, between 1996 and 2001 only one new drug launch of this category was achieved on average (Bolten and DeGregorio, 2002), and this decline in productivity proceeds (Kola and Landis, 2004). Despite of continuously raising R&D budgets, an increase in launched products could not be observed (Booth and Zimmel, 2004).

This productivity crisis has several causes. In the following the most relevant ones will be mentioned. First, the diseases remaining without satisfying treatments (e.g. cancer and neuro-degenerative illnesses) are much more complex than the others, because the underlying mechanisms are not completely understood, yet. Second, most of the traditional pharmaceutical companies are not able to integrate the emerging knowledge, e.g. of the genome information into their R&D processes. The capabilities to develop innovative therapeutic approaches are established mainly in biotechnology firms. Third, the regulatory authorities are more cautious and have extended their safety requirements in response to observed risks of already marketed drug that contributes to rising R&D costs (see the recent case of cox-2 inhibitors for treatment of arthritis).

In addition, the competitive situation of the pharmaceutical industry has worsened by the patent expiries of many blockbuster drugs and the immediate occurrence of more cost-effective generics that place a huge pres-

sure on the pharmaceutical industry, because the generics are gaining rapidly significant market share resulting in revenue decreases for the originators (Grabowski and Vernon, 1996). Thereby, many pharmaceutical companies are investing in their generic business to profit from the ongoing growth path of this product class (see Novartis and Pfizer). Furthermore, the efforts for cost-containment in public health care systems in combination with the political support of generics make the pharmaceutical business increasingly difficult.

The above mentioned innovation gap resulting from a lack of a promising drug pipeline represents the major problem. On the one hand, solutions are being pursued in mega-mergers to realize synergies as well as to combine R&D efforts and sales forces (e.g. Sanofi and Aventis). On the other hand, almost all pharmaceutical firms depend more or less significantly on strategic alliances with biotechnology companies and on in-licensed technology as well as therapeutic molecules that stem mostly from the biotechnology sector, too (Pavlou and Belsey, 2005). Another approach is represented by extending the usage of a certain drug to further application areas. This attempt to receive additional approvals for further indications is known as drug repositioning (Ashburn and Thor, 2004). Considering this difficult environment, the effective resource allocation to the most valuable R&D projects is, under these circumstances, one of the most challenging tasks of quantitative portfolio management. The basis for executing this task are appropriate and efficient project valuation methods.

In addition to the above mentioned factors, that shape the overall business of the pharmaceutical industry, the development of an innovative new drug is associated with many uncertainties. Within 10–15 years a new active substance has to complete a regulatory fixed sequence of R&D stages. Cumulated costs for this task amount to approximately \$ 900 million on average (Kaitin, 2003). The R&D process is marked by high attrition rates due to scientific failures. The so-called technical success probability achieves only 8% for a new drug (Gilbert et al., 2003) and is especially low in the first R&D stages. In addition to technical risks, the potential drug candidates also face the market risk that results from the unpredictable commercial performance after market introduction.

The entire R&D process is a highly regulated sequential procedure (see Fig. 1) starting with the so-called research stage that covers the biological validation of the drug target and the subsequent chemical optimisation of the potential drug candidate. Moving forward to early development, pre-clinical phase mainly comprises animal testing. Before entering the clinical phases an

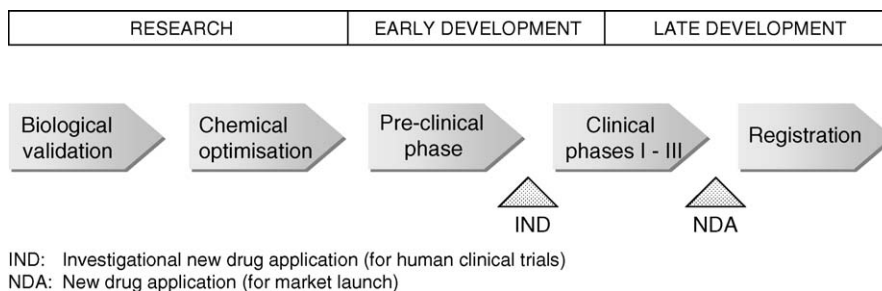


Fig. 1. The pharmaceutical R&D process, adapted from Mohr et al. (in press).

*investigational new drug application* must be submitted to the regulatory authorities. Following a positive decision, the compound is administered to healthy volunteers in clinical phase I to gather information about safety and dosage. In clinical phase II, application to a small number of patients is done to obtain proof of the concept. The next step of late development is characterised by clinical phase III studies that include a larger number of patients to ensure statistical significance. After successful completion, a *new drug application* is submitted to the regulatory authorities to be eventually admitted for market launch of the product candidate.

### 3. Real options analysis

In general, two different modi of usage of real options analysis (ROA) can be distinguished. Firstly, a utilisation can take place in a conceptual manner (real options reasoning, ROR) meaning that emphasis is attributed to the innovative management philosophy rather than to new calculation methods. This “application as a concept” aims to provide a more holistic analysis of the project features from an option’s perspective.

The second mode of usage is based on the first one. After identifying all relevant options, it is possible to employ the real option methodology for concrete valuation procedures (real options pricing, ROP). Here, two common techniques show practical importance. The first one refers to the famous Black/Scholes (B/S) equation (Black and Scholes, 1973; Merton, 1973) which offers an analytical (formula-based) and exact solution. The Geske model (Geske, 1979) provides an extension of B/S for the valuation of sequential options. The second but less common method is given by the so-called binominal lattice (Cox et al., 1979). Here, future cash flows are modelled in each time step by an up- or downward (binominal) movement whose extent is derived from the market volatility. Furthermore, binominal lattices offer widespread extension possibilities including

the accountance for both the technical risks as well as market uncertainties.

Furthermore, there are combinations of Expected Net Present Value (Kellogg and Charnes, 2000) and real options analysis referring to Smith and Nau (1995). These authors explained that under certain circumstances decision analysis and real options can lead to identical results. Emphasis is attributed to decision trees and the intensive investigation of the value drivers often integrated in a comprehensive risk assessment. Therefore, this concept facilitates the immediate application of the important essence of the real options considerations without the need for a fundamental change of current valuation techniques. For this purpose, there are various approaches especially from consultancies, e.g. PricewaterhouseCoopers (Krolle and Oßwald, 2001) and Bioscience Valuation (Bode-Greul, 2000). In addition, suitable software tools for structuring and valuing R&D projects in this manner are commercially available. In the following, we consider these hybrid methods also as a conceptual real options approach.

### 4. Evidence of practical application of real options analysis

#### 4.1. Inter-sectoral level

Until the end of the old millennium several international companies (e.g., Merck and Co., Boeing) reported the application of real options analysis. Referring to this data, some authors have already announced the “real options revolution” (Coy, 1999). Copeland and Antikarov expected in 2001 that the real options approach would convert into a standard method by the end of the current decade. In contrast to this overwhelming euphoria, actual inter-sectoral surveys uncovered a stagnate or even a decreasing dissemination of real options analysis. A survey of Bain and Co. in 2000 revealed that only 9% out of 451 participants use ROA while observing an abandonment rate of 32%

in this particular year (Teach, 2003). Ryan found in a sample of 205 *Fortune 1000* firms that only 11.4% use ROA as an auxiliary method compared to 96% for NPV (Ryan and Ryan, 2002).

The majority of real option-related empirical surveys concentrated on the conceptional level, meaning the novel management approach. Busby and Pitts (1997) showed for companies represented on the FTSE Index 100 that the higher management of the respective finance departments is aware of the presence of options inherent to the investment projects. Often, the embedded flexibility was mentioned as the crucial criterion for the investment. Valuation of these options was not executed with the real options pricing routines because the participants were not familiar with them. A further inter-sectoral study was conducted by Howell and Jägle (1997), also in England. The aim was to compare the correspondence of the intuitive real options valuation with the respective results derived from real options theory. The outcomes show clear differences in a direction towards an over-valuation by the participants. These differences were the lowest in real options branches as oil and pharma. Vollrath (2001) surveyed the capital budgeting approaches of the largest German companies and additional ones from real options branches including pharma. Real options are ranked at the lowest position. The knowledge of the real options approach constitutes 30–35% depending on the company level in question. The abandonment was explained by the complexity of the approach that resulted in a black box problem.

Another reason for the reluctance of ROA application is that sometimes RO are perceived and disgraced as a New Economy tool. However, this point is not valid if the application is done properly. In addition, implementation must be supplemented by organisational alterations that allow for and facilitate options thinking. Although, basic pricing (software) tools are available, now, it is always necessary to adjust them oneself significantly to the concrete sector and task in question.

#### 4.2. Sector-specific usage: the case of the pharmaceutical industry

Beyond the inter-sectoral evidence, the knowledge about the sector-specific application of ROA is extremely limited. In pharmaceutical R&D normally sufficient market and project data are available to make reliable assumptions about the associated uncertainties for the drug candidate as an important input parameter for real options analysis. In addition, a scientific- and engineering-oriented corporate culture is given that may facilitate reference to complex methods (Teach, 2003).

The implicit accountance for real options considerations in the pharmaceutical industry was shown recently by means of a statistical evaluation with respect to patents and the subsequent exploration of certain research directions between 1979 and 1995 (McGrath and Nerkar, 2004). Another implicit accountance for real options was publicized by Woerner and Grupp (2003) who revealed that the enterprise value (indicated by the share prices) of a sample of US biopharmaceutical companies can be considered as the value of a basket option on their R&D portfolios. Thereby, characteristic parameters of the risk neutral density function implied in observed share prices can be used as R&D return indicators to describe the perceived commercial potential of R&D by the capital markets. In spite of several pricing case studies published by academia so far (e.g. Kellogg and Charnes, 2000; Cassimon et al., 2004), empirical data of usage in daily routines are still lacking.

Only Merck and Co. reported the application of real options pricing with B/S with respect to valuation of biotech investments (Nichols, 1994). Remer et al. (2001) revealed that the real options approach is merely known and subsequently not applied in European biotechnology companies. These findings were confirmed by a small survey conducted by Lun and Peske (2002) by interviewing selected German biotechnology companies regarding their methods for investment analysis. Here, real option-based approaches show only a marginal role that might be due to the low grade of maturity of this sector in Germany resulting in the absence of specialised finance departments that apply sophisticated valuation tools regularly. Currently, industry experts propagate an integrative approach to project evaluation that also includes real options analysis (Jacob and Kwak, 2003).

## 5. Survey conception

The empirical results that will be presented in the next section were collected by a survey based on a written three-page questionnaire executed between February and October 2004. To obtain a holistic picture of the dissemination of real options analysis (ROA) in the pharmaceutical industry, we pursued a double-sided approach. On the one hand, we addressed companies from the pharmaceutical/biotech sector (in the following: pharmaceutical section) to capture the internal view of their R&D. On the other hand, we supplemented this by the external perspective of the health care divisions of investment banks, auditors and consultancies (in the following: capital market section). The first class concentrates more on private risks defined by technical success rates, whereas the latter focuses also on market-related

risks. By combining these two aspects, it is intended to yield a good approximation for the overall situation.

The survey range comprised leading international research-based pharmaceutical and biotech companies. They were selected following a top 50 company list ranked by sales in 2002 and 2003 (Sellers, 2003, 2004). The focus on the largest and most important companies was done due to the former findings of surveys with respect to smaller biotech companies that revealed a marginal usage of cutting edge project valuation approaches such as Expected Net Present Value and real options. Therefore, more sophisticated methods on cutting edge might be more likely to find in larger firms which maintain distinct departments for portfolio analysis. In total, 28 answers (out of 56) from participants stemming from the three most important markets Europe, USA and Japan (according to the headquarters location) were received (see Fig. 2A). The related sizes of the R&D departments and the company divisions covered by the answers are depicted in Fig. 2B and C, respectively. In the financial service section, we included national as well international companies by contacting the health care divisions, mainly of their German or European offices (distribution: see Fig. 2D). In this survey part, we received 27 (out of 56) responses. Although the answers are not supposed to be significant for the whole pharmaceutical sector, they have a clear importance for large international pharmaceutical companies by revealing important trends with respect to the usages of different methods for project valuation in general and real options in particular.

## 6. Survey results

### 6.1. Valuation methods

The first question regarding content referred to the valuation methods used for different valuation tasks. In order to provide an overview of the answers of the participants, the usage of each method by the participants is related to the number of answers. The resulting percentage was then categorised into four groups. A percentage that exceeded 50% was classified as a *main method* (most intensive grey background and white letters) used by the majority. Then, two kinds of auxiliary methods were defined. The first one, the so-called *auxiliary method I* (the second most intensive grey background), covers the area between 50% and 26% usage. The second one, the so-called *auxiliary method II* (the third most intensive grey background), comprises the values ranging from lower than 26% down to 11%. The remaining *niche methods* (lightest grey background) are negligible. Methods without any mentioning are excluded and not represented.

The results from the pharmaceutical section and the financial service companies are depicted in Tables 1 and 2, respectively. Except for the research phase, the survey clearly confirmed the assumed dominance of NPV-based valuation approaches in R&D in the pharmaceutical section. However, seemingly ROA also found its place in the method set with its peak usage lying in clinical phases. In contrast, ROA has absolutely no significance in the research stage. Here, while observing

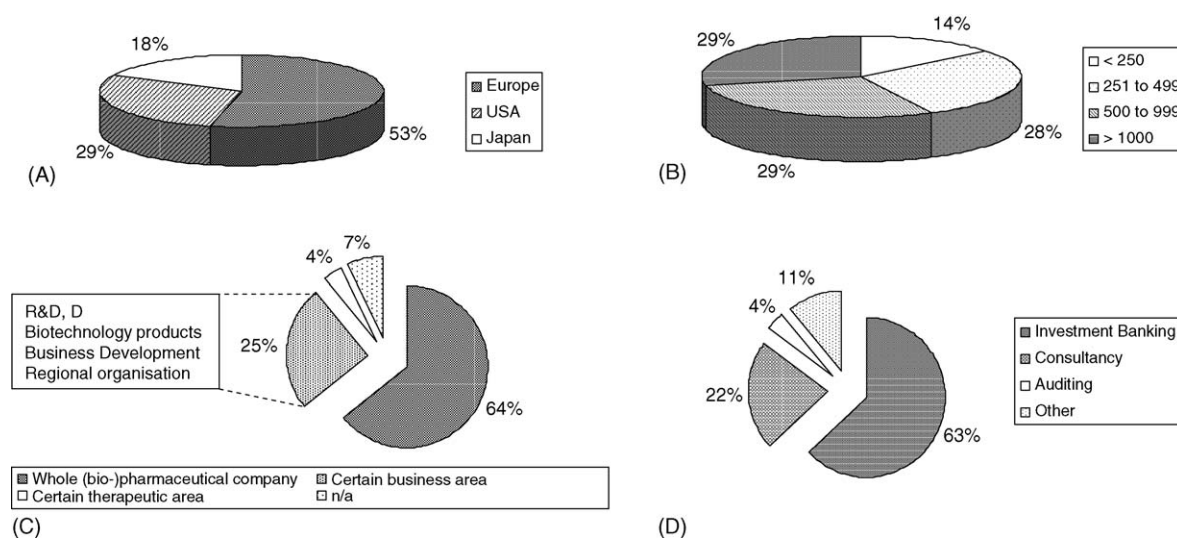


Fig. 2. (A) Regional distribution of the pharma participants according to location of headquarter. (B) Distribution of pharmaceutical R&D expenditures of the participants in 2003 (million Euro). (C) Pharma company divisions covered by the answers. (D) Distribution of the participants from the financial service section.

Table 1

Evaluation methods in the pharmaceutical section (E)NPV: (Expected) Net Present Value, DCF: Discounted Cash Flow, RoE: Return on Equity, RoI: Return on Investment, EVA<sup>®</sup>: Economic Value Added

	Valuation methods								Risk analysis and further criteria					Number of answers	
	NPV / ENPV / DCF	RoE / RoI / EVA <sup>®</sup>	Internal rate of return	Scoring model	Real options analysis	Net asset value	Capitalised earnings value	Multiples	Other	Monte Carlo simulation	Decision trees	Scenario analysis	Sensitivity analysis		Payback period
<b>R&amp;D stages</b>															
Research	59%	6%	18%	47%		6%		6%	6%	6%	29%	29%	18%	18%	17
Pre-clinic	76%	12%	24%	24%	12%	4%			4%	20%	56%	60%	48%	16%	25
Clinical phase I	85%	15%	27%	19%	23%	4%			4%	19%	69%	69%	69%	23%	26
Clinical phase II	100%	19%	22%	11%	26%	7%			7%	26%	74%	67%	74%	26%	27
Clinical phase III	100%	22%	30%	11%	26%	7%		4%	11%	33%	74%	67%	78%	30%	27
Registration	96%	21%	29%	8%	21%	8%		4%	13%	38%	71%	67%	75%	29%	24
<b>Company valuation</b>															
Early biotech	82%	18%	9%			9%	9%	27%	9%		18%	9%	45%	36%	11
pYoung biotech	89%	11%	11%			11%	11%	22%	11%		22%	22%	56%	56%	9
Old biotech	80%	40%	20%			20%					40%	80%	60%	40%	5

Table 2

Evaluation methods in the capital market service section (E)NPV: (Expected) Net Present Value, DCF: Discounted Cash Flow, RoE: Return on Equity, RoI: Return on Investment, EVA<sup>®</sup>: Economic Value Added

	Valuation methods								Risk analysis and further criteria						Number of answers		
	NPV / ENPV / DCF	RoE / RoI / EVA <sup>®</sup>	Internal rate of return	Scoring model	Real options analysis	Net asset value	Capitalised earnings value	Multiples	Other	Monte Carlo simulation	Decision trees	Scenario analysis	Sensitivity analysis	Payback period		Regression analysis	Other
<b>R&amp;D stages</b>																	
Research	73%	9%		36%	9%			9%		36%	45%	36%	45%	9%		11	
Pre-clinic	64%	9%		36%	27%					45%	45%	36%	45%	9%		11	
Clinical phase I	85%	15%		15%	23%			8%		38%	54%	46%	38%	8%		13	
Clinical phase II	89%	26%	5%	11%	16%	11%		11%	5%	26%	37%	53%	37%	5%	11%	19	
Clinical phase III	87%	22%	4%	9%	13%	9%		22%	4%	22%	30%	52%	35%	4%	9%	23	
Registration	78%	22%	4%	9%	9%	13%		26%		17%	26%	48%	35%	4%	10%	23	
<b>Company valuation</b>																	
Early biotech	71%	8%	6%	18%	18%	6%	6%	53%	6%	24%	17%	47%	53%	6%	12%	6%	17
Young biotech	74%	11%	5%	16%	16%	5%	5%	47%	11%	21%	16%	47%	47%	5%	16%	5%	19
Old biotech	85%	30%		15%	15%	10%	20%	75%	5%	15%	15%	50%	55%	5%	15%	5%	20
Small/medium pharma	70%	33%	4%	15%	11%	11%	15%	85%	7%	11%	7%	48%	52%	4%	11%	4%	27
Big Pharma	81%	38%	8%	15%	8%	12%	12%	58%	4%	12%	12%	50%	61%	4%	12%	4%	26

the lowest values for NPV, that keep their main methods status in spite of this, scoring models almost reach classification as a main method. Risk analysis is mainly provided by decision trees (DT), scenario and sensitivity analysis (that is valid for all phases). In addition, Monte Carlo simulation (MCS) and payback period have some dissemination. Again, the research stage delivers a different picture, described by a lower prevalence for all risk assessment approaches.

Company valuation, especially for early biotechs (not publicly listed and without marketed products) and young biotechs (publicly listed and without marketed products), shares many features with R&D project valuation due to the fact that their lead R&D compound accounts for the key value driver. However, even by considering mature biotech firms with marketed products (“old” biotechs) from the pharmaceutical section’s perspective, ROA usage was not detected in this setting. One organisational reason may be given by the fact that our participants main task was R&D portfolio management rather than company valuation, which is often executed by distinct M&A divisions together with investment banks and consultancies.

Switching to the capital market section, slight variations occur. Here, the clear dominance of NPV-based approaches in R&D project valuation is observed, too. Conversely, there is a little usage of ROA in the research stage while its peak utilisation is situated in the pre-clinical phase and clinical phase I, declining towards market introduction. Other important valuation methods are scoring models for research and pre-clinic projects, return on equity (RoE)/return on investment (RoI)/economic value added (EVA<sup>®</sup>) for clinical projects as well as multiples for clinical phase III and registration. Risk assessment is not performed as often as was observed in the pharmaceutical section, but also mainly covers MCS, DT, scenario and sensitivity analysis.

The capital market section additionally includes two further company valuation tasks, namely that of small- and medium-scale pharma as well as Big Pharma. Predominately for all company valuations are NPV-based approaches and multiples. ROA always amounts to auxiliary method II status. Only RoE, RoI and EVA<sup>®</sup> show some further importance for larger companies. Risk assessment concentrates more or less on scenario and sensitivity analysis.

## 6.2. Personalised medicine

After the completion of the decipheration of the human genome and the beginning of understanding the molecular basis of diseases, the establishment of a new era

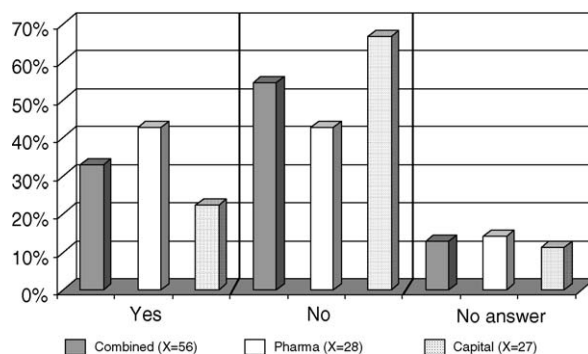


Fig. 3. Does personalised medicine require new project valuation methods?

of drug development is on the rise. Tailor-made drugs (pharmacogenomics) will probably replace or at least transform the current blockbuster business model in the mid to long term. The application areas of these future pharmaceutical compounds will be limited to certain patient sub-populations resulting in low(er) net present values. Much of their value will be contributed by growth options (e.g. broadening the therapeutic indication or the mode of administration). This raises the question whether new valuation methods are required to cope with these fundamental changes.

Interestingly, among the pharmaceutical companies a clear direction could not be observed. 43% answered the question with yes and the same amount with no. Indeed, it seems to represent an issue that future research has to deal with. The relatively high percentages of blank answers (15%) might be explained by low immediate importance of this issue that may render the involvement with a first example within the own company. In contrast, the capital community has a more clear feeling about this issue with a rejection rate of 67%. Only one third agrees with the hypothesis above. The majority of the combined sample does not follow this argumentation and considers the current tool set as sufficient. However, a remarkable amount sees the necessity for new methods (Fig. 3).

## 6.3. Knowledge and modi of usage of the real options approach

The first reported practical application of real options pricing of a pharmaceutical company stems from Merck and Co. (Nichols, 1994). Since then, several examples and case studies were presented by academia. In addition, real options theory is taught in almost all MBA courses and standard textbooks on corporate finance cover this topic. However, does this mean that all companies are familiar with this new approach and that they have dealt intensively with its relevance or even use it?

Table 3  
Knowledge of real options analysis (ROA)

Level of ROA knowledge	Pharmaceutical section	Capital market section	Combined
No knowledge	14	7	11
Known by name	14	33	24
Contents known	43	37	40
Application: real options reasoning	11	11	11
Application: real options pricing	18	11	15

All numbers in percent.

Table 3 answers this question. Within the pharmaceutical company section, 15% have no knowledge about real options analysis. All these answers stem from R&D functions associated with project management. The same percentage only knows them by name. On the other hand, 44% have dealt at least with the underlying theory and its implications. Finally, only 26% have implemented real options analysis in their daily routines. 15% apply the instrumental real options approach and 11% the conceptual one.

In the capital market section the overall knowledge of real options analysis is slightly higher. Only 7% have not heard about it, so far. A 33% are familiar with at least the name. However, the discussion of the contents, reaching 37%, is less common than in the pharmaceutical section. Regarding ROA usage, there are no major differences between the two groups, although real options pricing appears to be somewhat more common in the pharmaceutical section.

It can be concluded that overall level of knowledge is relatively high. However, the significant difference

between the share of companies that have dealt with the theory and those few that have implemented real options analysis raises the next question regarding the reasons for this reluctance.

6.4. Obstacles for the usage of real options analysis

To elucidate the hindrance reasons for the initial or further employment of real options analysis, a large variety of potential reasons were given to the participants. Fig. 4 shows the outcome to this question. The topics are ranked by their number of enumeration yielded by the overall survey sample. To simply compare the differences between the two subgroups, they are also included separately.

The far most relevant aspects are provided by the assumed complexity of the real options approach and the lack of acceptance from decision-makers and customers. There is almost no difference between the pharmaceutical and the financial service companies. Lack of transparency and lack of options pricing knowledge are also nearly equally distributed within the two subgroups with a small tendency for pharmaceutical firms to be more critical. Satisfaction with existing methods is higher for the pharmaceutical companies whereas the financial service firms are more concerned about the non-standard method character of real options pricing. Reliability and integration into existing models are further criteria that are raised more from the pharmaceutical side. On the other hand, the implementation expenditures are considered as very high, preferably by the financial service companies. This might be explained by the consequent orientation to customers external to the company of these firms. In contrast, valuations inside pharmaceutical com-

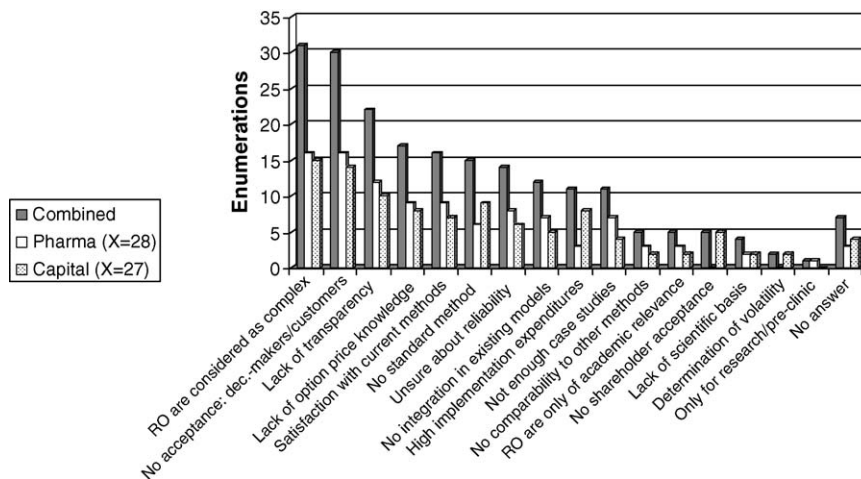


Fig. 4. Reasons for reluctant (further) usage of real option pricing.

panies are exclusively used internally as decision support for the higher management.

Especially the pharmaceutical section wants to see more case studies. The reason for this apparently lies in the heterogeneity of the applied real options pricing methods published so far. Furthermore, the quality of the case studies presented to date, are not satisfactory at all regarding the complex situation in the pharmaceutical environment, e.g., different scenarios with respective distinct features and competition challenges to be modelled. Surprisingly, there is very little mention of concerns regarding the methodical point of view compared to organisational aspects. The scientific basis of real options pricing was put to question only three times as well as the difficult determination of the appropriate volatility (twice).

### 6.5. Comparison of the real options approach to the NPV method

Due to the fact that reliance was mentioned as an important problem of the real options calculation results, the levels of predictability of RO and NPV, respectively, were compared on a scale ranging from 0 (poor) to 10 (excellent). Within the pharmaceutical section the preference for the NPV approach is obvious and clear: 6.4 versus 5.4. In contrast, the financial service companies see almost no differences regarding predictability between the two methods: 5.8 (NPV) versus 5.6 (ROP). Interestingly, the value for the NPV is clearly lower than reported in the pharmaceutical section and the variance of the answers for the RO value in the capital market section is 50% higher than that for NPV, whereas in the pharmaceutical section these values are almost equal. This indicates that a clear picture of the RO approach has not been formed, so far, especially within the financial service companies.

## 6.6. Real options pricing

### 6.6.1. R&D project valuation

In the entire Section 6, multiple answers were possible. Here, the participants were questioned concerning the concrete real options pricing (ROP) methods that are used or intended to be used for valuation purposes. Fig. 5 shows that in the pharmaceutical section a higher tendency occurs for the application of Black/Scholes in project valuation as it is stated by the financial service companies. This represents an interesting point due to the fact that the B/S equation is not able to capture the technical risk of an R&D project directly. The more flexible lattice-based approaches are preferred by the capital

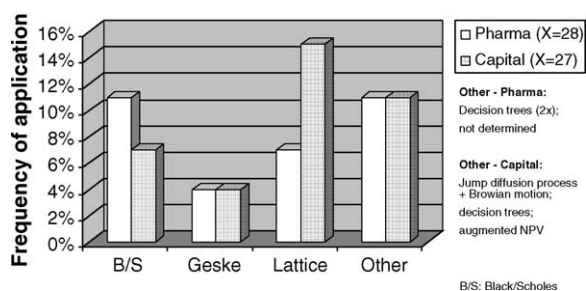


Fig. 5. Methods of real options pricing for R&D projects.

market section. The Geske model plays in both cases only a niche role. Decision trees were mentioned several times as methods for options pricing. This refers to the mixed approaches described in Section 3.

### 6.6.2. Company valuation

Turning to company valuation, the highest prevalence is attributed to Black/Scholes method, although lattice-based approaches still have some relevance. From the pharmaceutical section very little feedback was received due to the fact that this valuation task is often executed in other specialised departments or in collaboration with consultants. Therefore, the focus should be directed to the answers from the capital market section (Fig. 6).

### 6.6.3. Volatility determination in R&D project valuation

Due to the fact that volatility accounts for the most difficult variable to be determined and represents the key value driver in options pricing, the last technical question deals with this parameter. The results show that the pharmaceutical section relies on expert opinions and own calculations obtained by sensitivity and scenario analysis (see Fig. 7), whereas the financial service firms apply stock volatility, especially from biotechs. In addition, the usage of benchmarks and historical data is stated. Presumably, this contrary distribution is based on the availability of relevant information. The internal data, restricted to the respective pharmaceutical company, are

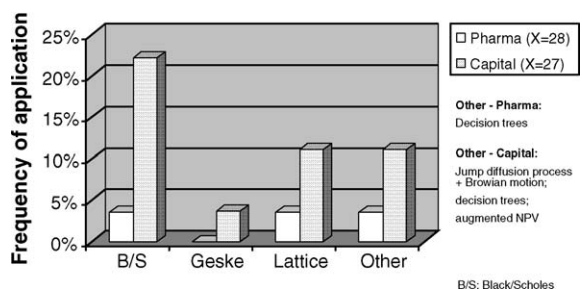


Fig. 6. Methods of real options pricing for company valuation.

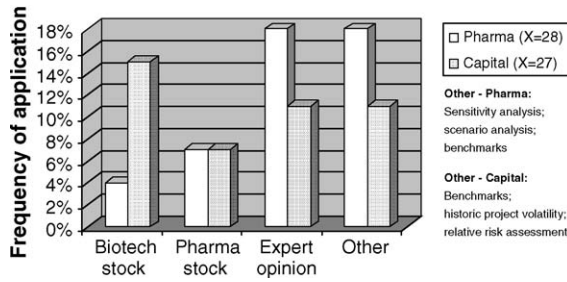


Fig. 7. Determination of volatility – R&D project valuation.

likely to provide more detailed information than the historic stock volatility which has the advantage of being publicly available.

6.6.4. Volatility determination in company valuation

More prominent than for project valuation, the volatility for company valuation stems from the historic stock volatility of biotech and pharma shares (Fig. 8). However, expert opinions still retain some importance. Here again, the participation of the pharmaceutical subgroup was very low, following the discussion in Section 6.1.

6.7. The future of real options pricing

The last questions deal with the future prospects of real options pricing. Firstly, an outlook on the possibility for a more frequent use of it is undertaken in the respective company. The second question applies to the sector level and refers to the statement of Copeland and Antikarov presented in the introduction.

6.7.1. The future of real options pricing in the own company

A vast majority of both the pharmaceutical and the capital market section do not intend to initiate or extend the application of ROP. Only for the clinical phases there might be a slight increase that is more pronounced in the pharmaceutical sector (Fig. 9).

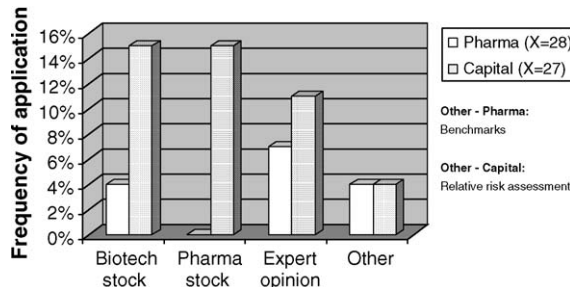


Fig. 8. Determination of volatility – company valuation.

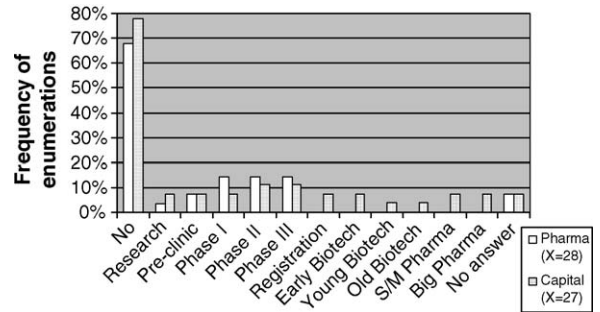


Fig. 9. Near term introduction or extended usage of ROP for different valuation tasks.

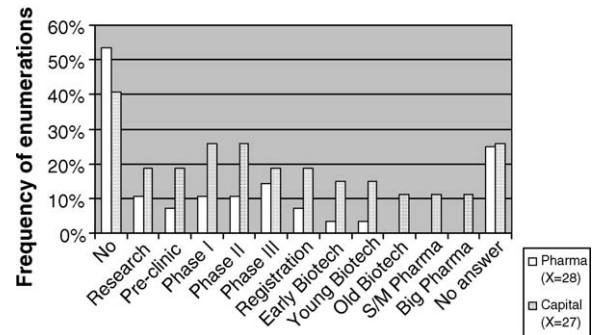


Fig. 10. Judgement if ROP will develop into a standard method for different valuation tasks by 2010.

6.7.2. The future of real options pricing of the sector level in 2010

Here, the situation changed dramatically. While there is almost no change within the impressions from the pharmaceutical sector, the financial service firms regard ROR much more positively with respect to their future importance. A peak is reached for clinical phases I and II with 26%. All other R&D stages amount to 19%. In addition, the high percentage of blank answers must be noted. These participants obviously did not dare to make a guess for the future perhaps due to the fact that they have little or even no knowledge about ROR (Fig. 10).

7. Discussion and outlook

The results convincingly show that the “real options revolution” anticipated by Coy (1999) has not become true so far for valuation tasks in pharmaceutical R&D within the sample companies. Based on the information that was provided to us, this event is not expected to happen in the mid-term, if ever. On the other hand, real options are not obsolete in the pharmaceutical industry as other inter-sectoral surveys (Ryan and Ryan, 2002; Teach, 2003) suggested. According to our empirical research, this relatively new method has found its place

as an auxiliary tool in the valuation set applied in this sector as suggested by Jacob and Kwak (2003).

The focus of the application of the real options approach by the pharmaceutical companies lies in the clinical phases, whereas in the financial service firms, the highest values are observed in the pre-clinical phase and clinical phases I/II. Overall usage is more often reported from the pharmaceutical firms, although the capital market section sees real options more likely as a standard valuation method in 2010. However, short-term application will not increase to such an extent that the NPV approach will lose its dominance. A further support might be gained by the onset of personalised medicine. Although, here, the concrete consequences remain unforeseeable; the judgement especially from the pharmaceutical section might suggest an alteration in the actual method set for R&D project valuation.

Another result that can be drawn from the survey is that the application of ROA as a concept is gaining favour, because it provides a more holistic project analysis without the necessity to change current valuation methods fundamentally. The knowledge of the theoretical foundations of real options analysis in the pharmaceutical section seems even slightly better than that stated by the financial service companies. In accordance with former studies (e.g. Vollrath, 2001), both sections have in common that despite having dealt with the approach they often decided themselves against its implementation. In most cases this is due to the assumed complexity of this tool and – going along with this argument – the resulting lack of acceptance by decision-makers or customers. This negative picture may be because of a fixation on the best known real options technique namely Black/Scholes reported by Merck and Co. (Nichols, 1994). Other less sophisticated techniques such as binominal lattices presented for pharmaceutical R&D (e.g. Kellogg and Charnes, 2000) still lack attention.

Regarding the different real options pricing techniques, it is obvious that a standardisation has not taken place in pharmaceutical R&D so far due to the fact that – in some cases – different case studies present different approaches. However, there seems to be a tendency in academia and the consultancy sector towards the binominal lattices (e.g. Copeland and Tufano, 2004) that combine the abandonment of graduate mathematics and the possibility to include the technical risk of a project provided by its success rate. Indeed, academia is challenged to develop more adequate models to boost acceptance. Finally, the question will not be to replace the NPV approach by real options pricing. In contrast, the aim should be a more realistic view of the advantages

and disadvantages of both methods as well as using the right methods for the right tasks.

Further research has to deal with the particular environment for ROA in other sectors to elucidate the detailed situation there, beyond rough and simplified insights provided by inter-sectoral surveys.

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## References

- Ashburn, T.T., Thor, K.B., 2004. Drug repositioning: identifying and developing new uses for existing drugs. *Nature Review Drug Discovery* 3, 673–683.
- Black, F., Scholes, M., 1973. The pricing of options and corporate liabilities. *Journal of Political Economy* 81, 637–659.
- Bode-Greul, K., 2000. Real options evaluation in pharmaceutical R&D: a new approach to financial project evaluation, Surrey.
- Bolten, B.M., DeGregorio, T., 2002. Trends in development cycles. *Nature Reviews Drug Discovery* 1, 335–336.
- Booth, B., Zimmel, R., 2004. Prospects for productivity. *Nature Reviews Drug Discovery* 3, 451–456.
- Busby, J.S., Pitts, C.G., 1997. Real options in practice: an explanatory survey of how finance officers deal with flexibility in capital appraisal. *Management Accounting Research* 8, 169–184.
- Cassimon, D., Engelen, P.J., Thomassen, L., Van Wouwe, M., 2004. The valuation of a NDA using a 6-fold compound option. *Research Policy* 33, 41–51.
- Copeland, T., Antikarov, V., 2001. *Real Options: A Practitioner's Guide*, Texere.
- Copeland, T., Tufano, P., 2004. A real-world way to manage real options. *Harvard Business Review* 82, 90–99.
- Cox, J., Ross, S., Rubinstein, M., 1979. Option pricing: a simplified approach. *Journal of Financial Economics* 7, 229–264.
- Coy, P., 1999. Exploiting uncertainty: the “real-options” revolution in decision-making. *Business Week* 7, 118.
- Geske, R., 1979. The valuation of compound options. *Journal of Financial Economics* 7, 63–81.
- Gilbert, J., Henske, P., Singh, A., 2003. Rebuilding big pharma's business model. *In Vivo: The Business & Medicine Report* 21 (10), 1–10.
- Grabowski, H., Vernon, J., 1996. Longer patents for increased generic competition in the U.S.: the Waxman-Hatch Act after one decade. *Pharmacoeconomics* 10, 110–123.
- Howell, S.D., Jägle, A.J., 1997. Laboratory evidence on how managers intuitively value real growth options. *Journal of Business Finance and Accounting* 24, 915–935.
- Jacob, W.F., Kwak, Y.H., 2003. In search of innovative techniques to evaluate pharmaceutical R&D projects. *Technovation* 23, 291–296.
- Kaitin, K.I., 2003. Post-approval R&D raises total drug development costs to \$ 897 million. *Tufts Center for the Study of Drug Development Impact Report 2003*, vol. 5.
- Kellogg, D., Charnes, J.M., 2000. Real options valuation for a biotechnology company. *Financial Analysts' Journal* 56, 76–87.
- Kola, I., Landis, J., 2004. Can the pharmaceutical industry reduce attrition rates? *Nature Reviews Drug Discovery* 3, 711–716.

- Krolle, S., Oßwald, U., 2001. Wertorientierte Strategieberatung mit Real Option Valuation™. *Finanzbetrieb* 3, 233–239.
- Kumaraswamy, A., 1998. An organizational real-options perspective of firms' R&D: Empirical evidence. Paper presented at the Second Annual Conference on Real Options, Theory Meets Practice, Chicago, June, 1998.
- Lun, K., Peske, T., 2002. Anwendung des Tools noch zögerlich: Realoptionen. *Wissenschaftsmanagement* 8, 34–39.
- McGrath, R.G., Nerkar, A., 2004. Real options reasoning and a new look at the investment strategies of pharmaceutical firms. *Strategic Management Journal* 25, 1–21.
- Merton, R.C., 1973. Theory of rational option pricing. *Bell Journal of Economics and Management Science* 4, 141–183.
- Mohr, R., Pacl, H., Hartmann, M., in press. Realize hidden value through timely portfolio decisions. *Research Technology Management*.
- Myers, S.C., 1984. Financial theory and financial strategy. *Interfaces* 14, 126–137.
- Newton, D.P., Paxson, D.A., Widdicks, M., 2004. Real R&D options. *International Journal of Management Reviews* 5/6, 113–130.
- Nichols, N., 1994. Scientific management at Merck: an interview with CFO Judy Lewent. *Harvard Business Review* 72, 89–99.
- Pavlou, A.K., Belsey, M.J., 2005. Biopharma licensing and M&A trends. *Nature Reviews Drug Discovery* 4, 273–274.
- Remer, S., Ang, S.H., Baden-Fuller, C., 2001. Dealing with uncertainties in the biotechnology industry: the use of real options reasoning. *Journal of Commercial Biotechnology* 8, 95–105.
- Ryan, P.A., Ryan, G.P., 2002. Capital budgeting practices of the Fortune 1000: How have things changed? *Journal of Business and Management* 8, 355–364.
- Sellers, L.J., 2003. Fourth annual Pharm Exec Top 50. *Pharmaceutical Executive* 23, 42–52.
- Sellers, L.J., 2004. Pharm Exec 50. *Pharmaceutical Executive* 24, 60–67.
- Smith, J.E., Nau, R.F., 1995. Valuing risky projects: Option pricing theory and decision analysis. *Management Science* 41, 795–816.
- Teach, E., 2003. Will options take root? *CFO online*, July 1st, pp. 73–76.
- Vollrath, R., 2001. Die Berücksichtigung von Handlungsflexibilität bei Investitionsentscheidungen – Eine empirische Untersuchung, in: Hommel, U., Scholich, M., Vollrath, R. (Eds.), Berlin.
- Woerner, S.D., Grupp, H., 2003. The derivation of R&D return indicators within a real options framework. *R&D Management* 33, 313–325.