

Annexe I

Modelling of profitability

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1 INTRODUCTION

1.1 In this annexe, we describe the results of financial modelling to understand the relationship between economic profitability and profitability measured according to the conventions used in the PPRS. Our assessment of the PPRS profit control is in Annexe H.

1.2 The economic profitability of a project or firm is conventionally measured by the internal rate of return (IRR) of the cash flows over the life of a project or firm, but it can also be expressed as an annual rate of return on capital.¹ As discussed in Annexe H, accounting measures of profitability (such as those used in the PPRS) may differ from economic profitability for a number of reasons:

- under the PPRS, intangibles including R&D are excluded from the definition of capital. But R&D has the economic characteristics of capital
- even if R&D is included as capital, conventional accounting approaches do not allow for the cost of capital foregone between the time the R&D expense is incurred and the time that net revenue starts to flow from successful drug development²
- conventional accounting approaches also tend to use a simple approach to depreciation, which may not reflect the profile of the net revenue generated, and
- costs, as measured under the PPRS, may differ from the costs actually incurred by companies.

The focus of this annexe is on understanding the impact of the first three factors, although the modelling does take into account the impact of some of the specific features of the PPRS.

1.3 Oxera developed the conceptual framework and carried out the financial modelling described in this annexe. Oxera developed a model to simulate the cash flows and accounting profits of a notional pharmaceutical firm, over different phases of product development, from the R&D stage up to the end of the patent life (in the case of successful products). Three measures of firm profitability were modelled: return on capital (ROC) where R&D is expensed, ROC where R&D is capitalised, and IRR over the life of the firm:

- the first measure (ROC where R&D is expensed) is the basic measure of profitability used in the PPRS
- the second measure (ROC where R&D is capitalised) reflects an amended approach to accounting profitability where R&D is added to capital at the time of expenditure and then depreciated on a straight line basis, and

¹ It can be expressed as an annual rate of return by defining economic depreciation appropriately, see chapter 12.6 of Brealey, R.A., Myers S.C. and Allen, F, '*Corporate Finance (eighth edition)*', McGraw Hill, 2006.

² This may be partially or fully offset if R&D is included in capital from the date of expenditure rather than the date at which net revenue starts to flow.

- the third measure (lifecycle IRR) shows the true economic profitability of the firm. It is this measure that, were it to be calculated for a specific firm, could be compared with that firm's cost of capital to determine whether the firm was making sufficient profits to attract capital on an ongoing basis (or indeed above-normal returns).

1.4 All three measures are reported on a real, pre-tax basis. Two clarificatory points need to be made regarding this analysis:

- first, it should be emphasised that the results presented here are generated by simulations, and are of an illustrative nature. The significant aspect of the research was not to assess profitability across the industry as a whole, but rather to understand the differences between the alternative measures, and the key factors driving these differences, including company-specific characteristics, and
- in this annexe, we are concerned with the measurement of profits and therefore the modelling abstracts from a number of features of the PPRS, including the marketing allowance. These features are considered in Annexe H.

1.5 The remainder of this annexe is structured as follows:

- chapter 2 provides further details regarding the model, its basis and the assumptions used
- chapter 3 explains the scenarios modelled
- chapter 4 presents the results, and
- chapter 5 concludes.

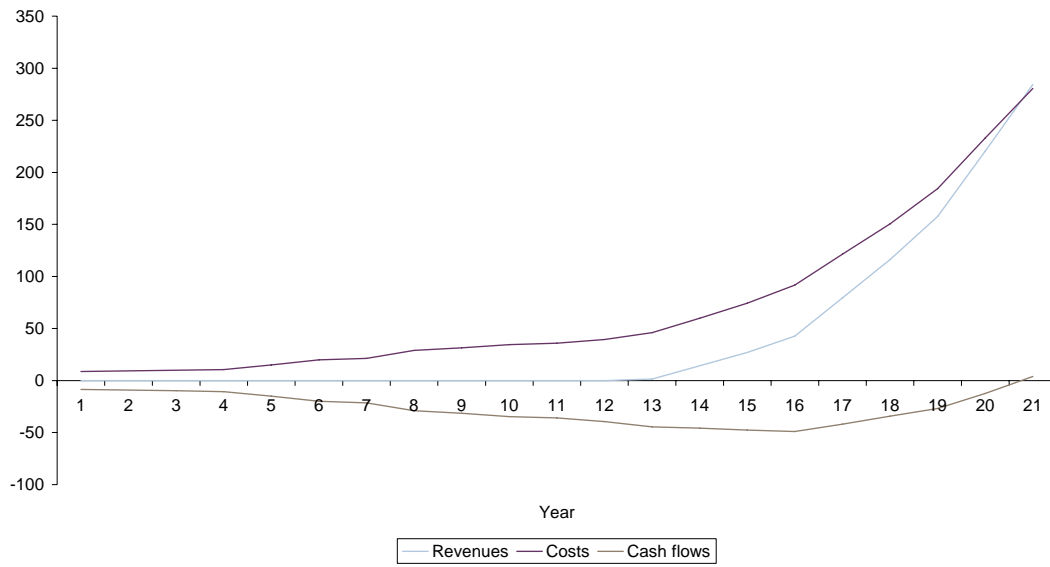
2 EXPLANATION OF THE MODEL

Overview

- 2.1 The model aims to capture some of the key features of the industry that are relevant to the relationship between accounting and economic profitability. In this chapter we set out the key modelling assumptions.
- 2.2 At a high level, the main features of the modelling are:
- a company is modelled as a portfolio of drug programmes
 - cash flows for each drug programme are generated over the whole lifecycle of a drug's development, starting from the initial decision to begin a research programme, followed by the costs incurred as the programme moves through each of the drug's development stages, along with the probabilities of success of moving from one stage to the next. Finally, the revenues associated with successful drugs are calculated
 - revenues and costs are assumed to increase by 7.4 per cent per year³
 - the cash flows from each individual drug programme aggregated to obtain the cash-flow of the company as a whole. It is assumed that the company exists for 100 years. For the first 75 years, it is assumed that the company creates new drug programmes. Thereafter, it begins no new programmes but continues to generate revenues and incur costs associated with previously commenced projects. By year 100, it is assumed that the company is wound up, having no remaining costs or revenues
 - the company cash flows are averaged over a large number of iterations (1,000). Average cash flows are then used to calculate the different profitability indicators. The ROC profitability indicators are calculated over the 40 year period from the year at which (on average) companies start becoming profitable—between years 20 and 59 of the company's life. This is intended to reflect the characteristics of companies whose profits are potentially controlled by the PPRS. The ROC is then compared with the lifetime IRR measure.
- 2.3 Figures 2.1 and 2.2 show the average revenues, costs (all costs, including capex) and net cash flows of the average company over its lifetime in the base case scenario of the model. In the first 12 years, the first drug programmes are still under development: consequently, revenue is zero and cash flow negative. From year 13, revenue increases rapidly as more drug programmes reach the marketing approval stage, and the average company becomes cash positive in year 21.

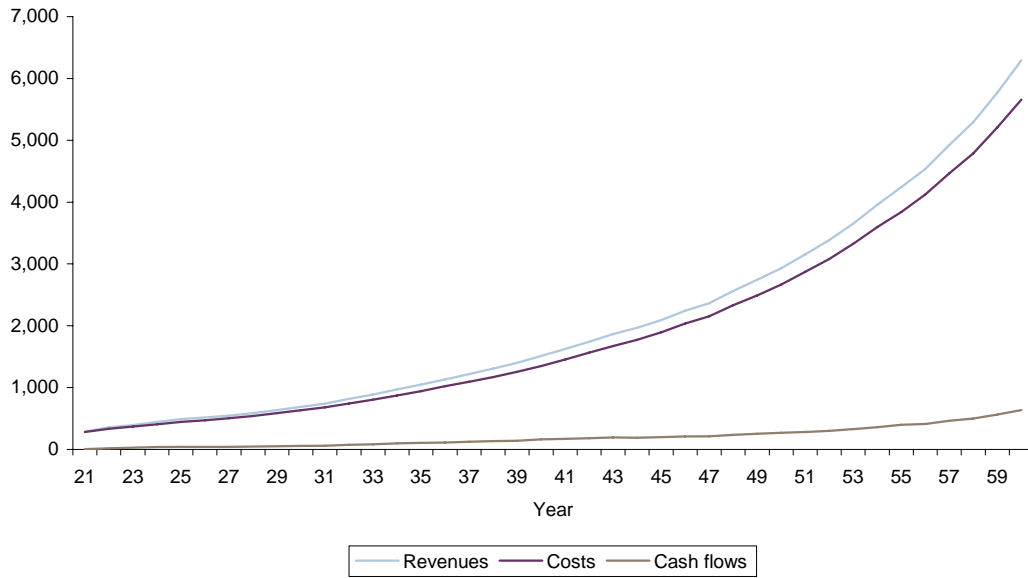
³ This assumption is based on the findings regarding recent trends in R&D costs in Di Masi, J, Hansen, R. and Grabowski, H. (2003) *The Price of Innovation: New Estimates of Drug Development Costs*, Journal of Health Economics, 22, 151–85. Other costs and revenue are assumed to grow at the same rate to maintain balance over time in cost structure and profitability.

Figure 2.1: Base case revenues, costs and net cash flows from the model (early years)



Source: Oxera modeling

Figure 2.2: Base case revenues, costs and net cash flows from the model (calibration period)



Source: Oxera modelling

Detailed assumptions

2.4 We now set out, at a more detailed level, the main assumptions used in the model.

Number of drug programmes

2.5 In the base case, it is assumed that each company starts four new drug programmes in each year.

R&D cost profile

2.6 It is assumed that the costs of an R&D programme are divided into six stages:

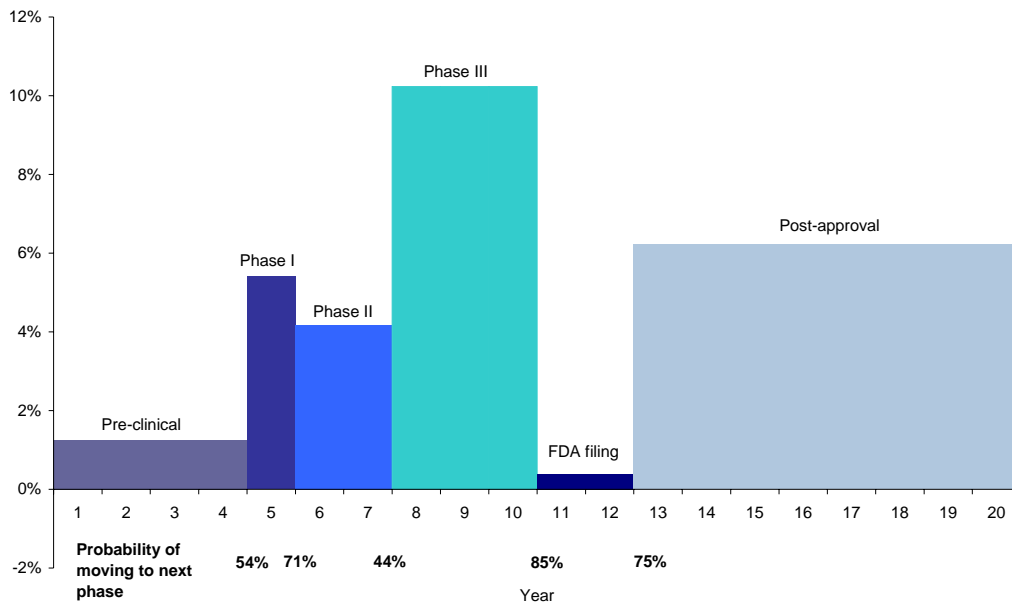
- pre-clinical research
- Phase I clinical trials
- Phase II clinical trials
- Phase III clinical trials
- post clinical trial but before marketing approval, and
- post-approval R&D, that is R&D carried out after the drug has obtained marketing approval and started to generate revenue.

2.7 At each stage, the probability of moving to the next stage is less than one, introducing a stochastic element to the model. In particular, the study explicitly models the success of each stage of every drugs programme.

2.8 It is assumed that each stage lasts for a certain number of years, and causes the company to incur a certain percentage of the total R&D expenditure associated with that drug (where the percentages are calculated assuming that the drug successfully passed each stage and was marketed, and where there is a certain probability of success in coming through each stage).

2.9 These various stages, and the annual average proportion of total R&D accounted for in each year of each stage, as well as the probability of moving from one phase to the next, are illustrated diagrammatically below.

Figure 2.3: Average annual proportion of total R&D spend accounted for in each year of an average successful drug programme



Source: Di Masi et al (2003) and Oxera assumptions

2.10 Figure 2.3 shows that the pre-clinical phase of drug development is assumed to last for four years, and that each of these first four years accounts for just over one per cent of the total monetary costs associated with a successful drug. At the end of year four there is then a 54 per cent chance of the stage being judged successful and hence of the drug programme moving into the next stage, Phase I. Each of the remaining stages of the drug programme can be interpreted in the same way. These probabilities and costs are sourced from (or calculated using) information included in Di Masi et al. (2003) and Healey et al. (1999).⁴

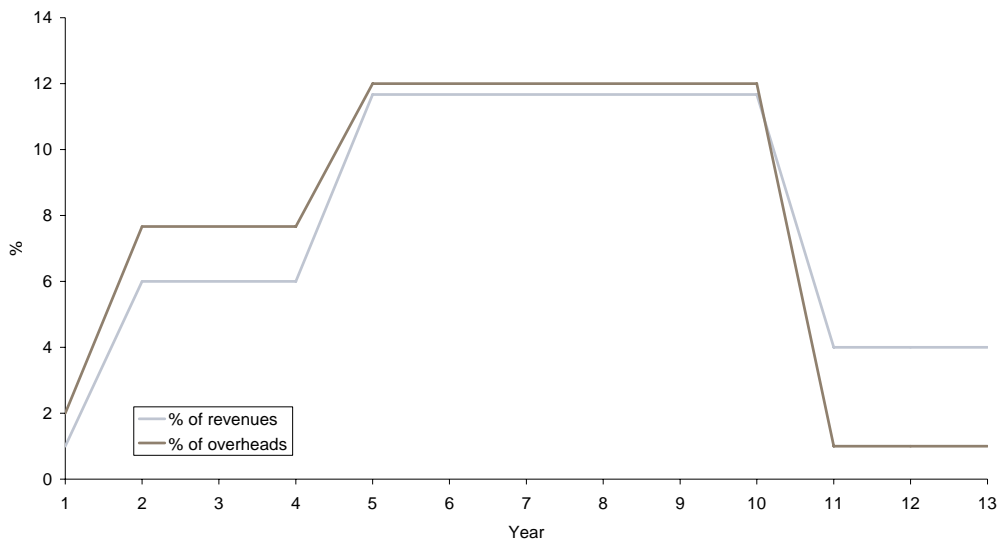
2.11 Figure 2.3 illustrates R&D expenditure for a successful drug programme. Of course, only successful drug programmes generate revenue and, for a company to be viable, revenue from successful drugs needs to cover R&D on both successful and unsuccessful drugs. Consequently, at a company level, the early stages of R&D (such as pre-clinical research which has a cumulative success probability of 11 per cent) are relatively more significant than suggested by the size of the boxes in Figure 2.3. Similarly, the later stages of R&D, particularly post-approval R&D, are relatively less significant than suggested by the size of the boxes in Figure 2.3.

⁴ Healey, P., Myers, S.C. and Howe, C.D. (1999), 'R&D Accounting and the Tradeoff between Relevance and Objectivity', mimeo.

Post-approval revenues and operating costs

- 2.12 If a drug programme successfully comes through the marketing approval process, it begins to generate revenues for the company—that is, revenues begin to be earned while the company is still undertaking post-approval R&D. At this point, the company must incur marketing and production costs associated with manufacturing the drug.
- 2.13 A distinction is made between 'average' drugs and 'breakthrough' drugs. The probability of a drug being a breakthrough drug—given that it has already come through all of the relevant R&D stages—is assumed to be 20 per cent. This introduces a further stochastic element to the model.
- 2.14 Figure 2.4 illustrates the assumptions made regarding post-approval revenue and overhead costs for an average drug, and Figure 2.5 illustrates the assumptions for a breakthrough drug. The profile of cost of goods sold (COGS) expenditure is assumed to be identical to that of sales revenue, so is not shown in the diagrams above.

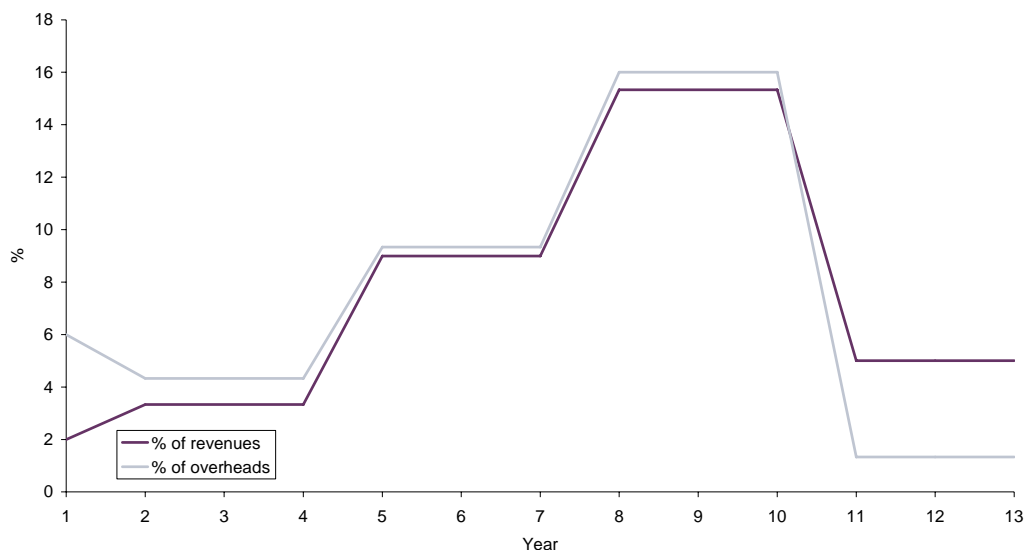
Figure 2.4: Profile of annual average revenues and overheads associated with an average drug



Source: Healey et al. (1999) and Oxera assumptions

- 2.15 Figure 2.4 shows that the percentage of total revenues and overhead costs assumed to be associated with 'averagely' successful drugs is relatively low in the years immediately after approval (around two per cent in the first year after approval). It then steadily increases, so that most revenues and overhead costs are generated between five and ten years after approval. As the drug nears the end of its patent life, the percentages of both variables fall away quite sharply.

Figure 2.5: Profile of annual average revenues and overheads associated with a 'breakthrough' drug



Source: Healey et al. (1999) and Oxera assumptions

2.16 Figure 2.5 illustrates that, for breakthrough drugs, the majority of costs and revenues are realised at a later point after approval. Revenues and costs are highest in the period eight to ten years after approval, where, annually, approximately 16 per cent of total costs and revenues associated with the programme are earned/incurred.

2.17 Our assumed profile of revenues and costs is sourced from Healey et al. (1999). We are however aware that the analysis of revenues and costs by Grabowski et al⁵ assumes that promotion and marketing costs are disproportionately high in the first two years, implying that positive cash flows on successful drugs arise somewhat later than implied by Figures 2.4 and 2.5.⁶

Capital expenditure and depreciation

2.18 In the base case, two types of capital expenditure (capex) are distinguished:

- **R&D capex**—that undertaken by the company for R&D activities—for example, capital investment in laboratories and associated equipment. This is assumed to be constant in each year of the company's life, and
- **manufacturing capex**—that required to produce drugs after they have successfully come through the R&D process. The amount expended is assumed to be proportional to the number of drugs the company has in the marketplace.

⁵ Grabowski, H., Vernon, J. and DiMasi, J.A. (2002), *Returns on Research and Development for 1990s New Drug Introductions*, *Pharmacoeconomics*, 20 Suppl. 3:11-29.

⁶ Figure 5 in Grabowski et al (2002) suggests cash flow remains negative in the first and second year after marketing approval.

2.19 Both types of capex are assumed to be depreciated on a straight-line basis over 20 years. In calculating ROC, with capitalised R&D, all R&D expenditure is also depreciated on a straight-line basis over 20 years.

Calibration exercise

2.20 The above assumptions are sourced from academic and professional literature. However, even after these assumptions have been made, there are a number of other 'free parameters', including:

- total R&D cost per drug over the full development stage
- total sales, COGS and overheads per successful drug, and
- capital expenditure.

Since we are interested in the relationship between measured profitability (ROC) and economic profitability (IRR) which depend on relative rather than absolute values of sales and costs, we can define costs relative to the level of sales

2.21 These ratios are determined through calibrating the model to reflect typical financial ratios/relationships that might be observed for pharmaceutical companies. The key ratios that are taken into account in the calibration exercise are presented in Table 2.1. Capital expenditure in the model is calculated from the ratio of sales to fixed assets shown in Table 2.1 and the split between 'R&D tangible' and 'manufacturing' capital expenditure from the assumptions set out above⁷.

Table 2.1: Ratios for calibration exercise (and base case assumptions)

Ratios	Weighted average values in base case (%)
R&D: sales	20
COGS: sales	40
Overheads: sales	20
Sales: fixed assets	110–130

Source: Oxera

Note: the range for sales to fixed assets reflects equally-weighted and value-weighted averages for ROC companies using data from AFRs

2.22 These ratios were based as far as possible on available data, for instance from companies' annual financial returns submitted under the PPRS (AFRs). However, we noted the following additional points:

⁷ Annual R&D tangible capex was assumed to be constant over time, starting in year 1, and annual manufacturing capex was assumed to be proportional to the number of drugs in the market in a given year

- two studies suggest that, at global level, the ratio of GOGS to sales might be rather less than our 40 per cent calibration assumption: Reinhardt⁸ suggests that pharmaceutical manufacturing costs account for about 27 per cent of sales value, while Danzon⁹ suggests global manufacturing and distribution expenditure represents 25 to 26 per cent of total costs (including cost of capital). However, these studies also suggest that sales, general and administrative costs represent 35 per cent of sales/total costs, which is more than our 20 per cent calibration assumption for overheads to sales
- as regards R&D intensity, our base case assumption (20 per cent) is somewhat in excess of the global average, which is around 15 per cent to 16 per cent of sales. Data from the DTI's R&D scoreboard suggest R&D intensity for pharmaceutical groups averages about 15 per cent but most of the groups include other activities as well as prescription only medicines. Data from the Pharmaceuticals Research and Manufacturers of America (quoted by the Congressional Budget Office) suggest an average R&D intensity of about 16 per cent for US pharmaceuticals companies. However, both estimates may slightly understate global R&D intensity, albeit for different reasons—(DTI scoreboard figures because they represent group totals which may include activities with lower R&D intensity than pharmaceuticals and PhRMA estimates because they include the sales of US subsidiaries of non-US companies but may exclude most of the underlying R&D of such companies if done outside the US¹⁰.

⁸ Reinhardt, U. (2001), *'Perspectives on the Pharmaceutical Industry'*, Health Affairs, 20:5, 141.

⁹ Danzon, P. (1997), *'Price Discrimination for Pharmaceuticals: Welfare Effects in the US and EU Industry'*, International Journal of the Economics of Business, Vol 4, No 3, 1997.

¹⁰ PhRMA figure also show the US R&D of PhRMA members was 18 to 19 per cent of US sales. However, this is likely to overstate global R&D intensity of US-owned companies if they do most of their R&D in the US, and there is no obvious reason why this precisely offsets any understatement of R&D intensity of non US-owned PhRMA members.

3 SCENARIOS MODELLED

3.1 In addition to the base case (described in the previous chapter), we modelled a number of sensitivities (summarised in Table 3.1 below). In broad terms, these can be divided into three categories: scenarios relating to company attributes, scenarios seeking to reflect certain features of the PPRS, and scenarios covering residual assumptions.

Table 3.1: Sensitivity scenarios

Category of sensitivity	Actual sensitivity
Different company attributes	Assuming that nominal costs and revenues remain constant rather than growth at 7.4% Changing R&D to sales ratio from 20% to 15% and 28% Having a profile of drugs that 'ramps up' and 'ramps down' through the assumed lifecycle Altering the (constant) number of drugs programmes started in each year to analyse how variance of profitability may vary across size of company
PPRS features	Reducing COGS by 10% and 20% Examining how the lifecycle IRR may be improved by considering lifecycle IRR with an R&D to sales ratio of 15% yet using a higher ratio for calculating expensed ROC
Residual assumptions	Changing start-up capex profile Altering the calibration period

Source: Oxera

Different company attributes

3.2 The first set of sensitivities relates to the idea that, within the pharmaceutical sector, there is considerable diversity in firms in relation to, for example, size and growth rate. Capturing all these differences would be difficult and would result in losing some of the 'general' conclusions. Nonetheless, we considered four 'alternative' features of firms, as detailed below:

- instead of assuming that costs and revenues increased by 7.4 per cent in real terms, it was assumed that they were stable in real terms
- the impact on the profitability measures of altering the R&D to sales ratio of companies from 20 per cent to both 15 per cent and 28 per cent was considered, while maintaining a constant number of drugs programmes started in each year, reflecting the idea that firms may differ in the nature of their research programmes
- reflecting the possibility that different types of company may undertake different types of research programme, a sensitivity was tested whereby instead of starting the same number of drugs programmes each year (four), there was a 'ramping up' and 'ramping down' of R&D activity through the lifecycle. Specifically, one drug programme was started in years one to ten; two programmes in years 11–20;

three programmes in years 21–30; four programmes in years 31–45; three programmes in years 46–55; two programmes in years 56–65; one programme in years 66–75; and none in years 76–100, and

- finally, instead of assuming that companies started four drug programmes per annum, it was assumed that they started up to 20. The objective of this sensitivity was to consider the extent to which the variance in profitability differs across different sizes of company, as captured by the number of drug programmes started.

3.3 In interpreting the results of these sensitivities, a limitation is that the other parameters have not been adjusted to maintain economic profitability at a plausible level (thus, as shown in Table 4.2 below, the effect of assuming no growth in costs and revenue is to reduce the IRR from 10.1 to 3.5 per cent). Nonetheless, the results do provide useful information on the sensitivity of the difference between profitability measures to different characteristics of firm type.

PPRS features

3.4 The second set of sensitivities investigates in more detail the impact that certain features of the PPRS might have on the difference between profitability measures. Two sensitivities are included within this category:

- first, as set out in Annexe H, PPRS profitability calculations may overstate costs (in particular COGS), for example due to biases associated with transfer pricing. In the light of this, we considered the sensitivity of the IRR to a 10 per cent and 20 per cent reduction in COGS. Under these sensitivities, the COGS/sales ratio is reduced from 40 to 36 or 32 per cent. Although, this is still in excess of the 25 to 27 per cent global ratio suggested by the studies referenced in paragraph 2.23, we have not made any adjustment to allow for higher selling, general and administrative expenses also suggested in those studies
- second, one of the key features of the PPRS is that, in regard to the profit maximum, it allows companies to claim R&D expenditure of up to 25 per cent of sales (28 per cent including paediatric allowance), despite the fact that the global average for R&D expenditure is considerably lower (see paragraph 2.23). The second sensitivity that is tested, therefore, is to assess the impact on the IRR of lower R&D expenditure.

3.5 For each of these sensitivities, the idea behind the modelling is to understand the extent to which these effects impact on the difference between economic profitability (IRR) and accounting profitability (ROC). Therefore, these sensitivities are assessed by considering how much the IRR changes without altering the unexpensed ROC.

Residual assumptions

3.6 The third set of sensitivities relates to particular features of the model where we wished to investigate the effect of changing the assumptions. Two sensitivities fall into this category:

- in the base case, the profile of manufacturing capex is proportional to the number of drugs the company has in the market. However, it is difficult to gain a precise understanding of the profile that manufacturing capex might take. The alternative scenario considered involves a fixed amount of manufacturing capex in each year, from the point at which the company first sells a drug to the point at which it begins to wind down
- in the base case, the model is calibrated, and ROCs calculated, between years 20 and 59. As an alternative, the model is calibrated, and ROCs calculated, over years 30 to 69, when the firm is close to steady state.

4 RESULTS

4.1 Following the structure set out above, the results are presented in four parts:

- estimation of the expensed ROCs, capitalised ROCs and lifecycle IRRs under the base case assumptions
- assessment of the impact that the diversity of firms (for example, in terms of the growth in R&D costs) is likely to have on the relationship between different ROC measures and lifecycle IRRs
- estimation of the sensitivity of the ROC and IRR measures to issues arising out of how the PPRS is designed and implemented, and
- assessment of the sensitivity of the key findings to the assumptions about the profile of firms' manufacturing capex and choice of calibration period.

Base case

4.2 The base-case results are presented in Table 4.1. Under the base case assumptions, the model generates an IRR of 10.1 per cent, close to our estimated cost of capital (see Annexe H). The expensed ROC, at 19.4 per cent, is almost double the IRR, although the capitalised ROC (11.6 per cent) is considerably closer to the IRR.

Table 4.1: Base-case measures (%)

	Expensed ROCs	Capitalised ROCs	Lifecycle IRRs
Base case	19.4	11.6	10.1

Source: Oxera calculations

Sensitivities relating to company attributes

Changes in costs and revenues

4.3 The first sensitivity considered is in relation to changes in costs and revenues. The assumption that costs and revenues grow (by 7.4 per cent per annum) can have potentially significant implications for the economic profitability of firms. The effects of this are highly complex but the main points are as follows:

- the expensing approach omits R&D from the capital base and hence understates the amount of capital compared to the economic level. This is true irrespective of the rate of growth
- with no growth, economic depreciation of R&D tends to equal or exceed R&D expenditure and thus the level of profits under the expensing approach is similar to

or higher than the level of economic profits.¹¹ However, with growth in R&D expenditure, annual R&D expenditure is increased relative to economic depreciation. Hence, profits under the expensing approach tend to be lower relative to economic profits, compared to the situation in the absence of growth. Thus, the result of growth in R&D expenditure is that the expensed ROC (profits/capital) is overstated less compared to economic profitability

- under the capitalised ROC approach, the effects are smaller and more complex but similar in direction. In the absence of growth, capital and depreciation tend to be understated compared to economic levels due to not allowing for the cost of capital foregone between the time of expenditure and the time at which economic profits accrue. With growth, both capital and depreciation are increased relative to economic levels, and consequently ROC is overstated less.

4.4 Table 4.2 shows that the wedge between the expensing ROC and IRR is strongly related to the level of growth in various costs and revenues of the firm. In particular, when measured using identical inputs, it shows that, with stable R&D costs (and other costs and revenues), expensed ROC is 4.7 times higher than the IRR (compared to 1.9 times higher in the base case). Similarly, capitalised ROC is 50 per cent overstated with no growth in costs and revenues, compared to only 15 per cent overstated in the base case.

Table 4.2: Impact of changes in growth in costs and revenues (%)

	Expensed ROCs	Capitalised	Lifecycle IRRs
Base case	19.4	11.6	10.1
No growth in costs	16.3	5.3	3.5

Source: Oxera calculations

4.5 Thus, the relationship (or wedge) between expensed ROCs and economic profitability depends on the growth of costs and revenues. This implies that a profit cap based on an expensed ROC can have very different implications on the allowed level of 'economic profitability', depending on firm characteristics.

Changes in the R&D to sales ratio

4.6 The next sensitivity considered is altering the R&D to sales ratio of companies. It is important to note what is being assessed in this scenario. The scenario examines the impact of the profitability measures of different R&D intensities for a given number (four) of projects started in each year. In other words, it can be perceived as reflecting

¹¹ With a fixed economic depreciation profile and ignoring lags between the time of R&D expenditure and of depreciation, in any year, economic depreciation of R&D is a weighted average of previous R&D expenditures and will consequently be similar to R&D expenditure if R&D expenditure is not growing. With lags between the time of R&D expenditure and of depreciation, allowing for the cost of capital foregone means that economic depreciation will tend to exceed R&D expenditure if R&D expenditure is not growing.

the margin that the company makes on each R&D project started, with an R&D to sales ratio of 15 per cent representing higher profit margins on each programme started (lower R&D costs for the same number of projects started), and a ratio of 28 per cent representing a lower profit margin.

Table 4.3: Impact of changes in the R&D to sales ratio (%)

	Expensed ROCs	Capitalised ROCs	Lifecycle IRRs
Base case	19.4	11.6	10.1
R&D: sales of 0.15	27.4	16.1	12.2
R&D: sales of 0.28	9.3	7.8	8.1

Source: Oxera calculations

4.7 The table shows that increasing the R&D to sales ratio from 0.2 to 0.28, for example, reduces firms' expensed ROCs from 19.4 per cent to 9.3 per cent. Similar effects are observed in the case of capitalised ROCs and lifecycle IRRs. The opposite effects take place when the R&D to sales ratio falls to 15 per cent. These effects are entirely as would be expected given the interpretation of the R&D to sales ratio as representing the profit margin made on the R&D—that is, firms that are able to develop the same number of R&D programmes at lower cost than other companies are more profitable.

4.8 However, as well as these anticipated directional changes in the measures of profitability, the wedge between the different profitability measures also changes in these sensitivities. With a higher R&D to sales ratio, the gap between the expensed ROC and capitalised ROC relative to IRR is reduced substantially such that the expensed ROC is only around 1.16 times greater than the IRR. By contrast, with a lower R&D to sales ratio, the wedge is much greater, at over 2.25 times higher.

Changes to profile of drugs programmes

4.9 The third sensitivity tested is one of altering the profile of the number of drugs programmes started in each year. Instead of assuming that a company starts the same number of drug programmes in each of the years of its assumed life, it is assumed that the profile follows the lifecycle of the company, starting with a small number of drug programmes, rising to a peak and then declining in the latter part of the company's lifecycle: one drug programme was started in years one to ten, two programmes in years 11–20, three programmes in years 21–30, four programmes in years 31–45, three programmes in years 46–55, two programmes in years 56–65, one programme in years 66–75, and none in years 76–100.

Table 4.4: Profitability measures under alternative profiles of drug programme commencement (%)

	Expensed ROCs	Capitalised ROCs	Lifecycle IRRs
Base case	19.4	11.6	10.1
Profiled number of drugs	17.6	13.2	11.7

Source: Oxera

- 4.10 The key point regarding this sensitivity is that it reduces the wedge between the different profitability measures. In absolute terms, the wedge between the measures is 5.6 percentage points, compared with 9.3 in the base case, while on a relative basis, the expenses ROC is only 1.5 times greater than the lifecycle IRR rather than 1.9 times in the base case. This is consistent with the finding regarding changes in costs and revenues discussed above: it was seen that, in the case that costs and revenues grow over time, the wedge between the profitability measures was less than if costs and revenues are flat. In this case, the wedge between the measures is further reduced as a result of the fact that, not only are the costs and revenues associated with each drug programme growing but, over the time in which profitability is assessed, so are the absolute number of drug programmes being started.

Absolute number of drugs programmes commenced

- 4.11 The final scenario examined within this subset concerned changes to the absolute number of drug programmes started in each year. The intention of this scenario was not to examine the changes in the resulting average profitability measures—it was anticipated that the average profitability would not change—but was instead to consider the variance of the profitability measure. This was to capture the idea discussed above that small companies may have a greater variability of returns over time and will therefore exceed the annual profit cap on a more frequent basis than other companies, even if long-run profitability rates are the same.
- 4.12 Given the purpose of examining this sensitivity, the results are presented in a slightly different format.

Table 4.5: Variance in the ROC measures for a different number of drug programmes started annually

Number of drug programmes started in each year	Average expensed ROC (%)	Variance of ROC (%)	Number of successful drugs in steady state
4	0.18	0.19	5.6
10	0.18	0.07	14.0
15	0.19	0.05	21.0
20	0.19	0.04	28.2

Source: Oxera

- 4.13 A preliminary point to note is that the average expensed ROCs are slightly different from those presented in the base case—that is, ranging from 18 per cent to 19 per cent rather than 19.4 per cent. This is due to the fact that, for computational reasons, it was necessary to calculate the results slightly differently: instead of averaging cash flows and then estimating ROCs based on average cash flows, ROCs are estimated for each simulation outturn and then averaged.
- 4.14 However, consistent with expectations, it is clear that the variance and standard deviation of the ROC measure decline significantly with the number of drug programmes started in each year. This decline in volatility would appear to be non-linear: the fall in the variance between starting four and ten programmes per annum is disproportionately greater than the decline between 10 and 20. This confirms that a company that starts a smaller number of drugs programmes in each year, and hence is a smaller company, is likely to exceed a profit cap on a more frequent basis than a company with the same long-run level of profitability but a broader portfolio of drugs.
- 4.15 It should be borne in mind that, in the model, a sustained period of negative profitability, which as shown above is more likely for small firms, does not result in the firm being removed from the modelling results. By contrast, in the real world, firms making consistently negative profits would be expected to exit the market. Under a binding profit control, this has the potential to lead to a survivorship bias problem where successful small firms have their profitability capped, as the success of these firms is not averaged out by the lack of success of other small firms, which is not observed.

Sensitivities relating to features of the PPRS

- 4.16 The approach taken to the assessment of profits within the PPRS leads to at least two ways in which assessed costs under the PPRS may be overstated (and hence profitability understated):
- COGS may be overstated, due for example to transfer pricing biases, and
 - companies can claim R&D expenditure up to the level of the allowance, which (in the calculation of maximum profit) is between 20 and 25 per cent of sales (and up to 28 per cent including paediatric allowance), and exceeds global R&D intensity.
- 4.17 To assess the possible impact of these factors, as mentioned above, a slightly different presentation approach is taken. First, the expensed ROC remains as in the base case, reflecting the current way in which profitability is measured in the PPRS. Second, for simplicity and to aid comparison, the capitalised ROC measures are not reported. Third, the IRR is recalculated to reflect a lower level of costs. The tables therefore show the possible magnitude of the impact that these factors may have on assessed profitability under the PPRS (where these factors are not captured) relative to the 'true' economic profitability of the firm.

Impact of over-reporting of COGS

- 4.18 Table 4.6 shows the effect on IRR of assuming a lower level of COGS. As expected, the expensed IRRs overstate profitability by less than in the base case.

Table 4.6: Sensitivity to assumptions on costs (%)

Change in cost of good sold	Expensed 'PPRS' ROCs	Lifecycle IRR	ROC:IRR
0% (base case)	19.4	10.1	1.92
-10%	19.4	10.9	1.78
-20%	19.4	11.7	1.66

Source: Oxera calculations

Altered R&D sales ratio for calculating lifecycle profitability

- 4.19 Table 4.7 illustrates the effect on the IRR of reducing the R&D to sales ratio by five percentage points (from 20 to 15 per cent). This broadly reflects the difference between the likely average R&D to sales ratio for calculating maximum profit under the 2005 PPRS (around 22 per cent, see Annexe H) and the likely average global ratio for pharmaceutical companies (we noted above (paragraph 2.23) two estimates suggesting global R&D intensity of 15 to 16 per cent but that these both might slightly understate true R&D intensity). In order to facilitate comparison, the IRR with the base case 20 per cent ratio is also presented.

Table 4.7: Changes to lifecycle IRR from altered R&D:sales ratio

	PPRS (expensed) ROCs (%) with 20% R&D to sales ratio	Lifecycle IRR with R&D to sales ratio as for expensed ROC (20%) (%)	Revised lifecycle IRRs with 15% R&D to sales:ratio ()	Original expensed ROC/IRR	Revised expensed ROC/IRR
Base case	19.4	10.1	12.2	1.92	1.59
No growth in costs and revenues	16.3	3.5	5.0	4.66	3.26
R&D allowance of 15% of NHS sales	27.4	12.2	12.2	2.25	2.25
R&D:sales allowance of 28% of NHS sales	9.3	8.1	12.2	1.15	0.76
Profiled number of drugs programmes	17.6	11.7	13.1	1.50	1.34
COGS reduced by 10% relative to reported (not for expensed ROC)	19.4	10.9	13.0	1.78	1.49
COGS reduced by 20% relative to reported (not for expensed ROC)	19.4	11.7	13.8	1.66	1.41

Source: Oxera calculations

4.20 As would be expected, using a lower R&D to sales ratio to compute the IRR than that used to compute the expensed ROC reduces the difference between the two measures in every case. Depending on the scenario, the increase in the IRR from using the global R&D to sales ratio is typically in the region of two percentage points. Indeed, with a PPRS R&D to sales ratio of 28 per cent, the expensed ROC is actually lower than the lifecycle IRR.

Residual assumptions

4.21 This section shows the effect of varying two of the modelling assumptions

Alternative capex profiles

4.22 First, the estimations are replicated under an alternative assumption on the profile of firms' manufacturing capex. Table 4.8 shows the profitability measures under the assumption that firms have no manufacturing capex in years 1–12 and a constant level of capex thereafter (instead of varying capex with the number of drugs on the market). It can be seen that the results of the simulation analysis remain relatively unchanged.

Table 4.8: Alternative capex profiles (%)

	Expensed ROCs	Capitalised ROCs	Lifecycle IRRs
Base case	19.4	11.6	10.1
Constant manufacturing assumption	17.1	10.9	9.7

Source: Oxera calculations

Alternative calibration periods

- 4.23 Second, Table 4.9 shows the simulation results under an alternative assumption about the calibration window. While the base case is based on the average ROC in the period between years 20 and 59, the table below shows the results for the case in which the company is considered to be in steady state—defined as having a stable ROC—which is between years 30 and 69. Again, it can be seen that the results remain relatively unchanged.

Table 4.9: Choice of calibration period (%)

	Expensed ROCs	Capitalised ROCs	Lifecycle IRRs
Base case	19.4	11.6	10.1
Steady state calibration period (years 30–69)	17.8	11.2	10.0

Source: Oxera calculations

5 CONCLUSIONS

Summary of model findings

5.1 The tables below summarise the results from the modelling exercise. Table 5.1 compares the results of the different profitability measures across the different scenarios, assuming that the inputs into the profitability assessment are the same for each measure. This provides a 'pure' comparison between the profitability measures.

Table 5.1: Summary of modelling results: comparison of abstract measures

Scenario	Expensed ROCs (%)	Capitalised ROCs (%)	Lifecycle IRRs (with same R&D to sales ratio as used for ROC calculations) (%)	Expensed ROC/IRR
Base case	19.4	11.6	10.1	1.92
No growth in costs and revenues	16.3	5.3	3.5	4.66
R&D: sales ratio of 15%	27.4	16.1	12.2	2.25
R&D: sales ratio of 28%	9.3	7.8	8.1	1.15
Profiled number of drugs programmes	17.6	13.2	11.7	1.50
Constant manufacturing assumption	17.1	10.9	9.7	1.76
Steady state calibration period (years 30–69)	17.0	10.4	9.2	1.85

Source: Oxera modelling

5.2 Table 5.2 additionally reflects the potential overstatement of costs under the PPRS. It illustrates how the ratio between the PPRS ROC and lifecycle IRR differs when:

- the lifecycle IRR is calculated on the basis of a 15 per cent R&D to sales ratio but the expensed ROC is calculated on the basis of a higher ratio, reflecting companies' ability to claim higher R&D costs under the PPRS, and
- the lifecycle IRR is calculated with COGS 10 per cent and 20 per cent lower than is used to calculate the PPRS ROC, reflecting the possibility that COGS may be overstated under the PPRS due for example to transfer pricing biases.

Table 5.2: Summary of modelling results: comparing PPRS ROCs and lifecycle IRRs

Scenario	PPRS ROCs (%) [*]	Lifecycle IRRs with 15% average R&D to sales ratio (%)	PPRS ROC/IRR
Base case	19.4	12.2	1.59
No growth in costs and revenues	16.3	5.0	3.26
PPRS R&D: sales allowance of 15%	27.4	12.2	2.25
PPRS R&D: sales allowance of 28%	9.3	12.2	0.76
Profiled number of drugs programmes	17.6	13.1	1.34
COGS overstated by 10% under PPRS	19.4	13.0	1.49
COGS overstated by 20% under PPRS	19.4	13.8	1.41

^{*} R&D to sales ratio is 20 per cent unless stated otherwise in left hand column.

Source: Oxera calculations

Overall conclusion

5.3 The modelling described in this annexe illustrates the difference between profitability measured under the PPRS and economic profitability. Some of the main points illustrated are:

- PPRS calculations of profitability do not capitalise R&D with the result that ROC tends to be overstated relative to economic profitability
- the relationship between PPRS profitability and economic profitability is sensitive to the assumptions underlying the modelling. In particular, it is highly sensitive to the underlying rate of growth in R&D and hence in sales. The higher is the rate of growth, the lower is PPRS profitability relative to economic profitability, and
- PPRS profits relative to economic profits also depends on detailed features of the PPRS, such as those associated with R&D and transfer pricing (see Annexe H). These reduce measured profitability and therefore tend to offset any overstatement of profitability due to not capitalising R&D.