Valuation for Licensing and Portfolio Management

The valuation of products, projects and intellectual property is a critical task for any successful healthcare company; here, the authors review the merits of the various different methods available and conclude that a combination of two offers the best approach.

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Whilst the market – through negotiations between sellers and buyers – will ultimately decide ‘value’ when products, projects or intellectual property are traded, there are methods available to estimate a rational basis for value.

Many traditional methods are crude and can even be dangerously misleading. At Bridgehead, we favour both simulation modelling and decision trees, and often use a combination. Both these methods effectively embody the advantages of option analysis, a modern financial method with the attraction of being tolerant of risk and long time-scales – unlike traditional discounted cash flow methods.

Whatever the method, the assumptions that underlie the calculation are key; these should be derived by thorough research and discussion with stakeholders.

Finally, benchmarking other deals with similarities in development stage, therapy area and parties involved will address the important question of market custom and practice.

INTRODUCTION

The variety of tasks facing valuers in the pharmaceutical, medical device, diagnostic and other healthcare product sectors is enormously diverse. They range from examining marketed products to estimating the worth of esoteric patent applications via valuing projects and technologies for decision making at various stages of risk and maturity.

One key area is licensing. When preparing a position prior to negotiation, in addition to benchmarking similar deals or following practice set by others, we believe that generating an internal view of value is an essential step towards:

♦ Justifying a position in negotiation of terms and ensuring equitable distribution of benefit, total
value for milestone and royalty amounts under various circumstances, and value to each party

- Deciding when a deal is appropriate (early/late?)
- Deciding what type of deal to target (front-loading needed?)
- Providing information for disputes over performance or early buy-out
- Valuing the product/deal as part of total corporate value

For most deals, the situation is complex and presents problems unique to the pharmaceutical arena, such as:

- Long time-scales: typically another 8-10 years to market and up to a further 12 years to peak sales
- Variability arising out of: uncertain product development probabilities (1) and cost (2); an inability to predict the exact final profile of any drug developed; unpredictable competition over long time-scales; changing – often adverse – political/social structures which affect the operating environment dramatically; the behaviour of a licensing partner over long time-periods and fluctuating company fortunes; and prediction of market response

Even when a product makes it through all these hurdles and reaches the market, it is not guaranteed success. Figure 1 shows that of all 39 products marketed into the prescription medicines sector in 1991 and 1992 in both Europe and the US, only eight have reached peak sales of over $500 million per year (3).

In addition to supporting licensing, the techniques reviewed in this article are also applied by the authors to other circumstances, such as portfolio reviews (R&D or marketed products), fund-raising and M&A activity. These areas can raise issues about non-financial value, which are beyond the scope of the current article. Examples include:

- Preferred corporate risk profile
- Effect on longer term (IPO/trade sale) valuation
- Acquisition of skills
- Importance of news flow

**VALUATION METHODS**

In this article, we look at six broad categories of approach to assessing and expressing value:

- Peak sales (future products)
- Sales multiples (current products)
Traditional net present value (NPV)
NPV simulation
Decision trees
Option pricing

Peak Sales
This method of forecasting the peak sales is based on an assessment of ‘similar’ products’ historical performance and vague market factors. It leads to statements like: ‘Product X is forecast to be a $500 million product’. It is used mostly by market analysts to give a snapshot picture. It has the advantage of being memorable and quick, but the disadvantage of being memorable even if wrong – as is often the case with such a crude method. It is not a true valuation approach.

Sales Multiples
This is used for products already on the market. The value is assumed to be a multiple of recent/immediate future sales, commonly 2-5 times. The advantage is that it is easy and clear to calculate, with scope for negotiation within the accepted range. As it is based on what the market pays, it is endorsed by practice and therefore inevitably plays a major role in negotiations. Although it can be shown that there is some relationship to an NPV calculation which considers product margins and future sales growth, it is another quite crude calculation and it may not be obvious to third parties why it applies.

Traditional Simple Discounted Cash Flow Method
This is an estimate of future annual cash flows to which is applied a discount rate that recognises both the cost of capital and risk. Sample discount rates used in pharmaceutical product development are:

- Preclinical 55-75%
- Phase I 40%
- Phase II 35%
- Phase III 20-25%
- Phase IV 15%

The annual discounted values are added together to reach a single NPV value.

Whilst widely used and apparently easy to calculate, this method gives only one cash value based on one set of assumptions. Given the uncertainty inherent in development, very many other assumptions are possible and valid.

There are three reasons we don’t recommend the traditional method. First, the discount rates have great power, but what is the right discount rate to use? (At a 25% discount rate, money earned in year 10, when a product might just be entering the market, is only worth 13% of its nominal value.) High discounting favours late expenditure and early revenues; this is the reverse of the drug development pattern and so can misleading. Second, the single figure result will almost certainly never happen – the final outcome is likely to be either much more or much less. Finally, the traditional method does not take account of the ability to change policy at a later date. For example, it includes all R&D costs even though later stages would not in practice be paid for if the product failed early.

Simulation Modelling
This approach overcomes all of the difficulties associated with traditional NPV calculations by permitting key assumptions to be entered as ranges of values with associated probabilities. Modern computing is so powerful that any office machine can run a programme with all key elements of the project; examples include development probabilities, market share estimates and price estimates.
As an example, price per month of treatment for a product could be set at: minimum $30, most likely $50 and maximum $60 – distributed in the form of a triangle. Launch date could be set at: 2009 (20% probability), 2010 (50% probability) and 2011 (30% probability).

To deal with these ranges the model is run many times, each time creating a new scenario derived by selecting a number from each range of inputs. Since many scenarios are generated, the model can also allow parts of a calculation to be switched on or off in an appropriate number of cases (for example, after success or failure in Phase II). If this particular switch is off, no further costs/revenues are calculated in that scenario. It is then possible to make an analysis across all the scenarios generated to give a range of results with associated probabilities; this can show an average result across all scenarios, which is itself meaningful, but still more usefully it can, for example, show that there is a 20% chance of the NPV of a project being above $75m, but a 35% chance that it will be below zero. This allows a risk assessment of an investment to be made.

A simple example of an outcome from such an analysis would be a chart of possible cumulative costs of a project, as shown in Figure 2.

While this simple analysis is in itself useful, the approach becomes particularly valuable when comparing across different strategic scenarios (see Figure 3). In the figure, the chart shows the probability (up the side) that values across the bottom will be met or exceeded (‘exceeded’ meaning being a more positive figure). So for Scenario D, there is an 80% chance that costs will be less than £12 million – which of course means that there is a 20% chance that they will be more. For Scenario C, there is no chance of costs being over £8m, and a 60% chance that they will be less than £4m.

When seeing this kind of analysis applied to a project NPV for the first time, many people are surprised that there are so many scenarios which are negative – but this is simply a natural consequence of the assumptions, and actual data, on project failure rates.

In the chart shown in Figure 4, the tallest column represents a negative – a project failure. It also reminds us of the gamble being taken in drug development – where wins can be big but so can losses – and illustrates the problem with traditional NPV methods which generally would produce one of the least likely outcomes. The probability of these same outcomes can also be displayed in the same way as in Figure 3; this is useful where comparison of projects is important (Figure 5).

There are some drawbacks to this approach. It is clearly rather more complex than the others described, and the results are not immediately understandable to everyone. There is an element of ‘black box’ mystery and, despite the sophistication, no modelling can take everything into account.

On the other hand, it has a number of advantages. It allows a variety of different views about important factors to be incorporated into a valuation; this is both clearly appropriate to so uncertain a situation, and a good way of gaining consensus across those involved about the assumptions used. It is possible to use low discount rates, generally reflecting the cost of capital, because all key risks are built into the model separately. As a result, it lacks the major distortions produced by traditional NPVs. It also allows decisions that will be made in the future – for example, about stopping a development project if poor results emerge – to be simulated. Finally, it produces both a financial result and a risk profile for that result, which adds huge value to the strategic decision-making process.
As a final word of caution – it is important not to be blinded by the technology. Like all models, a simulation is only as good as the data put into it. Applying clever methods to bad assumptions is doubly misleading. At Bridgehead, we spend a good deal more time generating high quality assumptions – often with primary market research – than building simulation models.

This technique is now widely recognised formally as a highly valid approach, and Bridgehead has been called on in a number of tax and litigation cases around the world to provide just this approach. US accounting standards encourage the use of this method.

**Decision Tree**

This approach builds a graphic representation of the decisions – or chance alternative outcomes – that can affect the overall value of a project. It shows the development of a project over time, with each main outcome itemised.

As with simulation modelling, discount rates are low because risk is dealt with by treating it as a probability of various outcomes at various stages, rather than by heavy discounting. This avoids the excessive reduction of late revenues that is found with the traditional NPV approach. It also allows the project to be stopped if bad results are achieved during development – taking any further R&D costs out of the equation in such an event.

Figure 6 shows a typical project valuation. It can be clearly seen how value (shown in the rectangular boxes at each node of the tree) increases as a project advances successfully. Equally importantly, it shows what may be lost at each stage, and the probability of this occurring.

The same project valued using traditional NPV methods would be worth only $9.9 million if it took six years to reach the market and a discount rate of 50% were used.

This simple, easy-to-understand graphic representation contains much of the most vital information about a project. The method is also flexible and can be used for valuation of a single project or to compare strategic options, for example in considering licensing terms or making portfolio decisions.

A comparison of three different approaches to the licensing of a late Phase I product is shown in Figure 7.

This tree not only shows the value of each alternative licensing approach, it also shows the risk profile of each. For example, the ‘co-development’ option has the highest value ($28 million) but also carries a 19% chance of losing $19 million and a 53% chance of losing $4 million.

Unlike simulation modelling, this method can only handle a relatively small number of variables (or the tree becomes a forest) and it does require some single point assumptions. It is however easy to understand and use, and again avoids the high discounts of the traditional NPV approach.
Real Options
In recent years, an attempt has been made to use a financial tool – Option Pricing – to value pharmaceutical projects. In an Option, the buyer pays a small initial price to acquire an option to pay a larger price at a later date to buy an asset at a pre-agreed price. This is similar to a company paying money now to carry out Phase II work, knowing it can later decide whether or not to carry out Phase III.

The principle is that there is positive value in having time to make a decision (because information will be better) and in having an interest in an asset that has a wide range of possible values (because you do not need to buy it if, over time, its value ends up in the lower part of its range).

This is attractive as it is exactly the opposite of traditional NPV calculation which punishes time by discounting and punishes variability in the value of the asset, because it is seen to introduce risk, leading to still higher discounts. As such, it is more in line with the development process for medical products.

The formal Options approach uses a single formula (named after Nobel Prize winners Black and Scholes) to derive a factor to apply to the value of the profit (asset) to be bought, and this requires the input of the following factors:

- The Present Value of the asset to be acquired (ultimate profits)
- The ultimate price to be paid for the asset if it is acquired
- The time before the decision to pay is made
- The risk-free rate of return
- The variability (volatility) of the ultimate income

This approach has been used in the pharmaceutical industry to value projects, most notably by Merck & Co (4). However in our view, the Black-Scholes formula presents problems (5) when applied to pharmaceuticals because, first, volatility of past market prices for comparable assets is a key input but, for medical research-based products, there is no trading record of this kind to provide a volatility estimate. Second, the method is designed for a commodity product where this asset price is the key variable; in pharmaceuticals, other variables which are not part of the Black-Scholes formula are also extremely important.

BENCHMARKING
In the licensing process, we cannot escape from benchmarking other deals with similarities in development stage, therapy area and parties involved. Doing this will address the important question of market custom and practice. Not only is this advisable as a sanity check on valuation calculations, it is a question that the other party will always raise – especially if it is favourable to their negotiating position.

A number of databases are available for this. Bridgehead itself is currently rolling out a series of products, having launched Partnering Week at the start of 2005 – a bulletin of deal terms published electronically every Wednesday.

CONCLUSION
Of the six valuation methods outlined above, methods 1 and 2 are useful in providing rough estimates, whereas method 3, traditional NPV, can be misleading.

At Bridgehead, we favour a combination of simulation modelling with decision trees. In practice, we have generated data which shows that both of these approaches essentially incorporate the Option concept. In other words, low discount rates are used, so that late earnings are not under-valued, and both permit projects to be abandoned if results are bad – that is, they allow for decisions to be made as time passes and information improves.

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References