# Real Option Valuation of a Pharmaceutical Company

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## Executive Summary

Valuing a research-driven firm is a challenging task. The static discounted cash flow (DCF) model fails to capture the value of R&D options. Pharmaceutical companies are, by their very nature, dependent on research products. These companies face an uncertain business environment. Roughly, one out of 10,000 explored chemicals becomes a prescription drug and only 30 per cent of drugs succeed in recovering their costs. Since the future of current R&D investments is uncertain, the traditional cash flow method may return a negative value of the future growth plan. Various studies have shown that the concept of real options can be applied to capture the value of R&D investments. Options give their owner the right (and not the obligation) to buy or sell assets at a pre-determined price (called the exercise or strike price) on or before an agreed expiry date. The underlying asset for which the option contract is made can be financial instruments (e.g., shares) or investment projects (e.g., expansion or acquisition or R&D investments). If the underlying assets are shares, such options are called 'stock options.' On the other hand, options on investment projects are known as 'real options.'

This study shows how we can value a pharmaceutical company with potential research products in the pipeline. The traditional DCF method could hardly explain around 39 per cent of the market capitalization of the company. This is because the market price has already factored in the growth options — the possible growth from drug discovery initiatives, growth from joint venture initiatives, etc. The cash flow model fails to capture these future values. Real options model to value research products has significantly improved the valuation. We show that the underlying value of R&D investments is best recognized in option pricing model.

With Indian patent laws following the footsteps of the WTO prescriptions (from 2005), Indian pharmaceutical companies cannot avoid making significant investments in R&D. The study reveals that unless the compounds under research have potential to be breakthrough drugs, it may be difficult to recover R&D investments. Therefore, attaining a reasonable global market share is critical for Indian pharmaceutical companies to exercise options. The Indian market for any high-investment research drug is comparatively small. Given the huge R&D costs of new drug discovery, it is impossible for a domestic manufacturer to recover the R&D costs from domestic sales. Capturing export market is vital to the success of any new drug. So far, not a single new drug has been fully developed in India (right from discovery to successful completion of all trials). Indian companies have acquired generic products, discovered alternative process of manufacturing a patented drug, and licensed out the compounds to multinational companies for clinical trials and commercialization. They have not taken the risk of completing the entire process of drug discovery on their own. But, things are changing now. Indian companies have realized the importance of having a strong R&D base and we may see some blockbuster drugs being manufactured in India. This, we hope, will further popularize the real options model of valuing R&D investments.

KEY WORDS

**Discounted Cash Flow**
**Drug Discovery Cycle**
**Option Pricing**
**Pharmaceutical Company**
**Real Options**

The market value of a company depends primarily on two factors—value of its current operations and value of future growth options. The value of current operations factors in the expected growth of current operations. Therefore, future growth options denote expected value from pipeline products / flexibility of operations. This is largely uncertain and hence very difficult to value. The traditional cash flow-based valuation only captures value of current operations and fails to justify the full market value. Since growth options are risky and at times need large investments, the traditional cash flow method may return a negative value of the future growth plan. A business also derives value from its flexibility of operations. For example, an automobile company may have to decide as to whether it should make significant investment in plant modernization which will enable the company to move towards a multi-product production platform from the present single-product production platform. If the company is currently producing only one variety of vehicles, justifying such significant investment for catering to the future needs (which may or may not arise) is not easy. Apparently such investment analysis may show negative net present value (NPV) and the project may get shelved. But, the flexibility of handling more products in future has an advantage. The question the company faces in such investment decision is, therefore, whether it would like to have the flexibility option. Another example could be justifying electronic banking network expansion for a bank where the results obtained using real options analysis enabled "the network's senior management to identify conditions for which entry into the POS (point-of-sale) debit market would be profitable"(Benaroch and Kauffman, 2000). The traditional approaches for evaluating information technology investments may produce the wrong recommendations. Answers to these two examples lie in the application of a popular concept called *real options*. Results obtained using real options analysis may provide evidence to justify such investments for flexibility and / or future growth.

A popular overview on the use and application of the concept of real options is available in Luehrman (1998) who mentions that a project which may appear to be a "marginal-to-terrible" project through a discounted cash flow (DCF) lens may appear to be an attractive one under option valuation analysis. Various other studies (Taudes, 1998; Kulatilaka, 1993; Perlitz; Peske and Schrank, 1999; Boer, 2000) have shown that the concept of real options can be applied to capture value of R&D investments in pharmaceutical industry, petroleum industry, industrial units, and even in the field of multi-media research. These studies have also shown that the DCF method cannot properly capture the options value in R&D. The extraordinary premium paid for technology stocks have caused observers to wonder whether traditional models of valuation are obsolete (Boer, 2000). The fact that market value of such stocks is primarily driven by future growth potential makes the DCF method appear as an "incomplete" method of business valuation. The DCF approach favours short-term projects in relatively certain markets over long-term and uncertain projects. This point is confirmed by Dixit and Pindyck (1995) who state that "the conventional NPV-Rule for capital budgeting only yields the same results as real option analysis when market and technology uncertainty tend to zero and the investment that is required for market introduction of the newly developed product is reversible." Managers intuitively use options in many business situations such as when they delay in completing an investment programme until the results of a pilot project are known (Amram and Kulatilaka, 1999). Real option models tend to give a scientific explanation to such "intuitive" valuations. For example, Merck's Finance Group used the Black-Scholes option-pricing model (Nichols, 1994) to determine the option value of an investment project (project Gamma) which required an up-front investment of $2 million in research for a bio-technological drug. Merck had the option to abandon the project at any time if dissatisfied with the progress of the research.

The present study applies the real option concept to value a pharmaceutical company in India. The study found that the traditional DCF method could hardly explain around 39 per cent of market capitalization of the company based on author's assumptions and estimates. This is because, for pharmaceutical companies, much of the market value is driven by milestones achieved in research which is not captured in DCF. The real option model to value pipeline products has improved the valuation. Similar results are observed in the US pharmaceutical industry (Amram, 2000), where cash flow from current products and operations could account for about 50 per cent of market value, while the remaining was thought of as future growth value from drug development activities.

## WHAT ARE REAL OPTIONS?

Options give their owner the right, without any obligation, to buy or sell assets at a pre-determined price, called the exercise or strike price, on or before an agreed expiry date. If the option gives a right to buy, it is called a 'call option' and an option with a right to sell in the future is called a 'put option.' The European options are exercisable on the maturity date while the American options can be exercised on or before the maturity date. The underlying asset for which the option contract is made can be financial instruments (e.g., shares) or investment projects (e.g., expansion or acquisition or R&D investments). If the underlying assets are shares, such options are called 'stock options.' On the other hand, options on investment projects are known as 'real options.' The beauty of the options approach of valuation lies in the fact that uncertainty (or volatility) of the future cash flows increases the option value. This is because options give the right but do not impose any obligation to honour the contract. Let us take an example.

An employee having a stock option to buy 100 shares of the employer-company after two years at an exercise price of Rs100 each (current market price) would exercise the call option only if the market price of share after two years is more than the exercise price (K). Suppose the market price ($S_t$) of each share of that company after two years is either Rs 150 or Rs 50. The value of the option on maturity is positive difference of the market price over the strike price or at the most zero [i.e., Max ($S_t$ – K, 0)]. So, when the market price is Rs 150, the value of the stock option (per share) is Rs 50, but when the expected market price is Rs 50, the value of the option is zero (i.e., the option is not exercised). We have considered here 50 per cent volatility. With a higher volatility of 75 per cent (i.e., market price could be as high as Rs 175 or as low as Rs 25), the value of stock option (per share) is Rs 75. So, higher the volatility, greater the value of option. However, there is an apparent error in this calculation. The present value of the option is not simply Max [$S_t$ – K, 0]. Exercise price is paid in the future, so we have to discount the exercise price (K) to find out its present value and it should be subtracted from the present value of underlying shares to arrive at the option value. So, volatility and discount factor would affect the option value.

In theory, different option valuation techniques are available (Geske and Shastri , 1985). The two most popular methods are Binomial method (BM) and Black-Scholes (BS) method. The first method uses the discrete time approach while the second one applies the continuous time approach. Thus, if the time intervals are small, the results obtained using BM converge to BS method. The BM is based on a simple representation of the evaluation of the value of the underlying asset in the form of a tree diagram and on risk-neutrality theory which implies every one is risk neutral, thereby eliminating the need to estimate risk premium. Cox, Ross and Rubinstein (1979) argued that the hedge position, viz., the combination of the option and the tracking portfolio earns a risk-free rate of return. The "risk neutral" assumption requires that the underlying asset is traded in a market that presents no arbitrage opportunities. Under this requirement, it is possible to construct a tracking portfolio of other traded assets that has the same risk as the underlying, where return on the portfolio must equal the risk-free interest rate ($r_f$). The BS model best suits the situation of continuous variations in asset value. It is a closed-form, neat, and single equation formula that computes the price of a call option for a risk-neutral investor.

The BS model for a European call option is given by:

$$C = S \cdot N(d_1) - K \cdot e^{-r_f \cdot t} \cdot N(d_2) \qquad (1)$$

$$d_1 = \{Ln(S/K) + (r_f + \delta^2/2) \cdot t\} / (\delta \cdot \sqrt{t})$$

$$d_2 = d_1 - \delta \cdot \sqrt{t}$$

In the above equation, 'S' is the value of an underlying asset that is assumed to be log-normally distributed (so as to avoid skewed structure with no negative values), 'K' is the exercise price, 't' is the time to expiration of option, 'δ' is the volatility of S and 'N(.)' is the cumulative normal distribution. Simply put, Equation 1 shows that $S_t$–K is the call's terminal in-the-money value, $S - K * e^{-r_f \cdot t}$ is the current in-the-money value of the call. To cover the case that the call might be unattractive to exercise, S and K are weighted by the probabilities $N(d_1)$ and $N(d_2)$ respectively (Benaroch and Kauffman, 2000).

Equation 1 also shows that the value of a call option will be higher

- the higher the value of underlying asset (S)
- the longer the time to expiration (t),
- the lower the exercise price (K)
- the higher the volatility of asset returns (δ)
- the higher the riskless interest rate ($r_f$).

Equation 1 has not, however, taken into account the dividend factor. In case of a stock option, the delay to exercise the call option will deprive the option holder of dividends and, thus, the present value of underlying share

to the holder of call option should be net of such expected dividends. If such dividends (constant) can be estimated for the life of the option, the value of underlying shares (S) should be adjusted. The adjustment is made by subtracting the present value of dividends foregone forever. Thus,

$$S^* = S - \sum_{t=1}^{n} D_t * e^{-r_f t}$$

So, a possibility of high dividend would prompt an American call option holder to exercise early to acquire ownership of the shares and receive dividend. But the holder of a European call option would lose due to such dividend payments by the company during the life of the option. This is because the European option cannot be exercised before the expiry date and hence the underlying value of the asset (i.e., share) has to be discounted. Thus, the BS Model (Equation 1) can be modified to incorporate dividend factor as below:

$$C = S \cdot e^{-d \cdot t} \cdot N(d'_1) - K.e^{-r_f \cdot t} \cdot N(d'_2) \qquad (2)$$

$$d'_1 = \{Ln(S/K) + [(r_f - D) + \delta^2/2]t\} / \delta \cdot \sqrt{t}$$

$$d'_2 = d'_1 - \delta \cdot \sqrt{t}$$

The argument for $d'_1$ (as different from $d_1$) is that since the total return for a risk-neutral investor is $r_f$, the expected growth rate in S must be $(r_f - D)$.

The BS model was developed to value stock options and not real options. But there exists a close analogy between real options and call options on stocks. In fact, the BS model can be suitably applied for real options valuation. The comparison of a call option on stock and a call option on an investment project is summarized in Table 1 (Trigeorgis, 1997).

## APPLICATION OF REAL OPTION VALUATION TO A PHARMACEUTICAL COMPANY

A research-driven pharmaceutical company derives greater value from its products in the pipeline or from drug discovery efficiency. It has been found that investment in R&D has a positive impact on the stock price (Lev, 1999). Much of the value in the early stages of a pharmaceutical project is contained in the promise that a blockbuster drug will result (Kellogg and Charnes, 2000). Pharmaceutical companies are in a peculiar situation—unless they invest in R&D, they cannot drive up stock price and the more they invest in R&D, the greater is the uncertainty. The Chief Financial Officer (CFO) of Merck once said, "The route to success is to put more money at risk, not less" (Nichols, 1994).

The value of a pharmaceutical company is derived from the expected cash flows of the company's existing products and potential value of pipeline drugs (out of R&D investments). The challenge lies in using real options valuation model to capture the potential value of current R&D investments. However, it is true that the real options framework assumes significance at the initial stage of R&D phase. As the drug development process approaches product launch stage, the uncertainty with respect to cash flow generating capacity of the product (under research) minimizes. The value of a company with real options can be shown as below:

Corporate value = Present value of free cash flow from existing products + Value of R&D investments (3)

In the following sections, we illustrate the application of Equation 3 in valuing a pharmaceutical company in India, viz., Dr Reddy's Laboratories Limited (DRL).

### Background of DRL

Dr K Anji Reddy and his associates incorporated DRL in 1984. Prior to 1994, DRL was known as a bulk drug manufacturer. Like other domestic pharmaceutical companies, DRL was mainly engaged in copying the molecular compositions of drugs discovered by multinationals. This was possible due to domestic patent laws. But, in 1994, DRL had set up its own research centre to shift the company's focus from copying generic drugs to developing research products. Within three years of

**Table 1: Comparison between Stock Options and Real Options**

| Variable | Stock Options | Real Options |
|---|---|---|
| Underlying asset (S) | Current value of stock | Present value of expected cash flows |
| Exercise price (K) | A fixed share price | Present value of investment cost |
| Time to expiration (t) | Fixed date (European option) | Time until opportunity disappears |
| Risk (volatility) (δ) | Stock value uncertainty | Project value uncertainty |
| Interest rate (r) | Risk-free rate corresponding to time to expiration | Risk-free rate corresponding to time to expiration |
| Convenience yield (D) | Dividend yield to shareholders | Payments lost through waiting to invest |

establishing the research centre, DRL filed 18 worldwide product patents for novel lead compounds. DRL's research is largely focused on the anti-cancer, anti-diabetes, and anti-inflammatory segments. The research arm of DRL is known as Dr Reddy's Research Foundation (DRF). During 1997-98, DRF discovered a new molecule to combat diabetes which the company claims to be superior to known insulin sensitizers. DRL has also acquired several brands from smaller pharmaceutical companies. Recently, it has acquired controlling stake in Cheminor Drugs Limited and American Remedies Limited. On the other hand, another major Indian pharmaceutical company's (Ranbaxy Laboratories Limited) first Investigational New Drug (IND) application is filed only in 1999. The share price of DRL in the beginning of 1994 was around Rs 213. It reached a low of Rs 164 in the beginning 1997, apparently due to no major breakthrough in research. At the end of 1998, it rose sharply to Rs 485, again perhaps due to a major breakthrough in anti-diabetes research during 1997-98. Thereafter, it reached a high of around Rs 1,500 just within one year. Such a sharp increase in the share price of DRL may be partly due to major milestones being reached in R&D. The DRL scrip has zoomed more than 100 per cent during April-July 2001 reaching Rs 1,870 on the Bombay Stock Exchange at the end of July 2001. During the same period, DRL's ADS (American Depository Shares) shot up nearly 143 per cent to US$24.6 from a listing price of US$10.10. One of the important reasons for such a spurt in share price, both in the domestic and international markets, is the grant of 180-day exclusivity in the US to market an off-patent version of the blockbuster anti-depressant Prozac. These movements in share prices intuitively imply that investors put greater value on the future growth potential (out of current research initiatives) of a pharmaceutical company (Figure 1).

## Cash Flow-based Value of DRL

The valuation of DRL on the basis of cash flow from its existing products as well as known acquisitions is done with the help of current available data and estimated trends for the future (Table 2). Table 2 is based on the following assumptions:

- Net sales = Gross sales – Indirect taxes.
- Cash operating costs denote before-tax operating costs excluding depreciation write-offs and amortizations. Cash operating costs (%) are expected to be maintained in the future. In fact, past five years cash operating costs (%) are also 75 per cent.
- Effective tax rate (provision for tax / profit before tax)

**Figure 1: Share Price Movements of DRL, July 1999-July 2001**

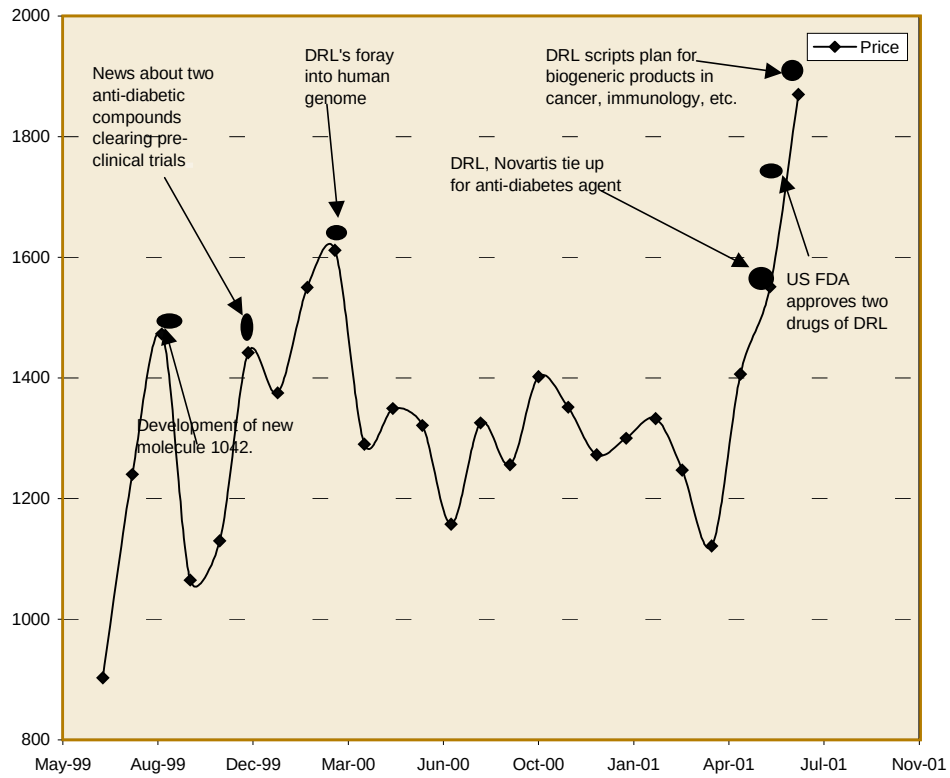


**Table 2: Necessary Inputs for Static Cash Flow Valuation**

| Description | 1999-2000 | 2000-2001 |
|---|---|---|
| Net sales (Rs million) | 4,378.96 | 8,324.19 |
| Cash operating costs (%) | 75.00 | 75.00 |
| Effective tax rate (%) | 35.00 | 10.00 |
| Working capital investment (% of net sales) | 20.00 | – |
| Capital expenditure (% of net sales) | 19.46 | 5.66 |
| Equity beta (on 60-monthly returns vs. Sensex) | 1.11 | 0.91 |
| Risk-free rate (364-days treasury bill rate) (%) | 10.08 | 9.86 |
| Expected risk premium (%) | 10.00 | 10.00 |
| Annual growth in sales (%) | 25.00 | 25.00 |
| Interest-bearing borrowings (Rs million) | 1,074.40 | 3,750.00 |
| Net worth (Rs million) | 4,351.70 | 6,462.48 |

**Source:** Prowess, CMIE, and www.drreddys.com

is estimated to be 30 per cent for the projected period (the effective tax rate for 2000-2001 is around 29%).

- Working capital (non-cash) investment (% of net sales) was averaging 20 per cent during the past ten years. We have assumed that it will be maintained at 20 per cent during the first five years of the projected period and 10 per cent thereafter.
- Capital expenditure (% of net sales) for the projected period is taken at 10 per cent (past 10 years average as well as average of immediate past three years). It is mentioned by the Chief Financial Officer of DRL that normal capital expenditure is to stay at the current level (www.drreddys.com / investor presentations.html).
- Long-term estimated risk premium is considered at 10 per cent (Banerjee, 2000). Indian companies (Satyam, Infosys, etc.) have used long-term estimated equity risk premium of 8 per cent in their EVA computation. We have used a higher rate.
- The company has witnessed yoy(year on year) growth in net sales of 25 per cent during 2000-2001.This yoy growth is computed on the basis of combined turnover of DRL and Cheminor Drugs (another company which is taken over by DRL during 2000-2001). It is assumed that projected period will witness similar growth rate. However, growth rate in sales beyond forecast horizon is taken at 5 per cent.
- Projected cash flow period is ten years.
- The decrease in equity beta in 2000-2001 may be due to many molecules entering clinical trial phase of research. As research approaches the maturity stage in developments (during 2000-2001, both the anti-cancer molecules under study have completed pre-clinical phase), the uncertainty reduces.

Based on data and assumptions in Table 2, the static cash flow value of DRL is computed for years 2000 and 2001. The results (Table 3) show that continuing value accounts for more than 50 per cent of the corporate value.

The assumptions used in this static valuation model are based on the past trends. However, non-cash working capital investments (% of net sales) and capital expenditure (% of net sales) in the future may not necessarily follow this trend. A sensitivity analysis shows that a 10 per cent change (increase) in working capital investments would adversely affect shareholder value by less than 1 per cent. But capital expenditure is more sensitive. A 10 per cent change in capital expenditure would have affected shareholder value by around 19 per cent. So, a different assumption for capital expenditure in future could substantially affect shareholder value of DRL. But, we have followed a conservative approach.

Table 3 shows that the static model could only explain around 39 per cent of market price as on March, 2001. In other words, a significant 61 per cent of the market price remains unexplained. This is because the market price has already factored in the growth options—the possible growth from drug discovery initiatives, growth from joint venture initiatives, etc. The cash flow model fails to capture these future values.

## REAL OPTION VALUATION FRAMEWORK

Merck & Company of the US had used real options framework to decide about its R&D investments and also to price acquisitions programmes (Nichols, 1994). Kellogg and Charnes (2000) have attempted to value one anti-HIV New Molecular Entity of a bio-technological company (Agouron Pharmaceuticals) by using Binomial Method. Perlitz, Peske and Schrank (1999) use a compound option model (Geske Model) to value R&D project of a pharmaceutical company. All these studies show that R&D investments are high-value and high-risk

**Table 3: Static Value of DRL**

(Figures in Rs million, unless stated otherwise)

| Sl. No. | Description | March 2000 | March 2001 |
|---|---|---|---|
| 1 | Cumulative present value of FCFF | 5,548.90 | 9,182.41 |
| 2 | Present value of continuing value | 4,739.89 | 10,311.55 |
| 3 | Corporate value | 10,288.79 | 19,493.95 |
| 4 | Interest-bearing debt | 1,074.40 | 3,833.10 |
| 5 | Market value of investments | 1,072.70 | 3.80 |
| 6 | Cash and bank balance | 219.10 | 194.40 |
| 7 | Shareholder value [3+5+6-4] | 10,506.20 | 15,859.05 |
| 8 | Number of shares ( million) | 26.49 | 31.58 |
| 9 | Value per share (Rs) | 396.46 | 495.60 |
| 10 | Mean closing(30-day) share price in BSE (Rs) | 1,464.42 | 1,287.93 |
| 11 | Static value (% of share price) | 27.07 | 38.48 |

**Note**

1. Pursuant to the amalgamation of M/s. Cheminor Drugs Limited, DRL issued 51,42,942 equity shares of Rs 10 each to the shareholders of M/s. Cheminor Drugs Limited (during 2000-2001) in the ratio of 9:25 as per the scheme of the amalgamation approved by the Hon'ble High Court of Andhra Pradesh.
2. Mean closing share price denotes 30-day average price of March (the last month of the accounting period).

propositions.

The drug development cycle of a pharmaceutical company for a researched drug shows that R&D is both time and cost intensive (Table 4).

The patent process takes 4-5 years time. Therefore, pharmaceutical companies apply for patent right after the discovery stage along with pre-clinical trial. In other words, a drug research company applies for patent registration once a molecule shows some promise of therapeutic effectiveness. This is done to ensure that patent registration is obtained when the research enters the clinical phase. Normally, Indian companies involved in therapeutic research apply for simultaneous patent registration in India (to Drugs Controller General of India) as well as in the US (Food and Drug Administration or FDA). FDA registration is a clear passport to the export market. The FDA process is more rigorous. However, drug authorities' approval has to be taken at each stage of clinical trials and only when all the three clinical trial phases are successfully completed can the product be launched. The patent period starts right from the day the patent is granted. Hence, the longer the clinical trial period (after patent registration), the shorter the unexpired patent period. The pharmaceutical company has to recover its costs and even profit within that protected patent period. It is, of course, true that even if the product goes off patent, revenues do not dry up. As per FDA norms, patents expire 20 years from the date of filing. Recent World Trade Organization norms also prescribe a product patent life of 20 years. This rule will be applicable in India from 2005. Therefore, the moment a patent application is filed with FDA after discovery stage, the clock starts and if the patent is granted after five years then only 15 years will be the unexpired patent period. If the researcher delays further due to clinical trials, the unexpired patent period gets even reduced.

**Table 4: Drug Discovery Cycle**

| R&D Stage | | Years in Stage |
|---|---|---|
| 1. Discovery of a molecule | | 1 |
| 2. Patent process initiated | | 4-5 |
| 3. Pre-clinical trials | | 4-15 |
| 4. Clinical trials | | 6-8 |
| Phase-I | 1-2 years | |
| Phase-II | 2-3 years | |
| Phase-III | 3 years | |
| 5. Registration (for marketing) | | 1-4 |
| **Total time (in years)** | | **12-28** |

**Source:** www.pfizer.com, Kellogg and Charnes, 2000.

It costs around US $350 million to US $500 million to develop a drug and the average time taken is 14 years (www.Pfizer.com and www.indiainfoline.com). This cost may be significantly lower for an Indian pharmaceutical company developing a drug in-house.

DRL has new molecules under discovery phase in three broad therapeutic segments—anti-cancer, anti-diabetes, and anti-inflammatory (Table 5).

The present study would only attempt to compute real options value of two anti-cancer compounds (DRF 1042 and DRF 1644) due to absence of necessary information relating to other compounds (or products). Though difficult, we have accessed different sources to gather necessary reliable information. The real options valuation shown here is strictly based on this information and certain assumptions. The results will differ under different assumptions. However, this valuation will drive home the fact that all these products under various stages of research (Table 5) have significant future value. After successful pre-clinical trials, these two anti-cancer compounds—DRF 1042 and DRF 1644—have been chosen

**Table 5: DRL's Important Pipeline Product Status**

| Therapeutic Segment | Product Code | Status |
|---|---|---|
| Anti-cancer | DRF 1042 | Clinical phase-I |
| | DRF 1644 | Pre-clinical (complete) |
| | DRF 3188 | Pre-clinical (last stage) |
| Anti-diabetes | DRF 2725 | Clinical phase-II (licensed out) |
| | DRF 2593 | Clinical phase-II (licensed out) |
| | DRF NPCC | Pre-clinical (complete) |
| Anti-inflammatory | DRF 4367 | Pre-clinical (complete) |

**Source:** Company's site: www.drreddys.com

for further development. An IND application has been filed in India for DRF 1042 and it has been recently approved for clinical trials. Clinical trials of DRF 1644 will be done in Europe. DRL has filed application with FDA for patent registration for both the compounds. The company has a critical care division which markets formulation drug. The entire current sales of the division come from oncology products. The division has registered a turnover of around Rs 150 million from its three anti-cancer products. These anti-cancer drugs are costly—for example, the price of one of the three drugs (Docetere) varies from Rs 2,250 (20 mg) to Rs 9,000 (80 mg). It implies that if the two compounds under trial successfully clear the R&D phase, they have the potential to earn significant revenues. Of course, it is true that the real value driver is net income and not gross revenue.

The input variables required to use Equation 2 of the BS Model for valuing options premium of DRF 1042 and DRF 1644 are discussed below:

### Underlying Asset Value

The BS Model uses continuously traded underlying assets (e.g., shares), for which continuous time series data are available. It is, therefore, relatively easy to derive value of this traded variable. In option pricing theory, it is important that the underlying asset is traded to carry out an arbitrage free evaluation. But, if the underlying asset is not traded (i.e., it has no market price), it is practically impossible to build a duplicate portfolio to determine the option value (Trigeorgis, 1993). In case of R&D projects, the underlying investment is not traded and hence market value cannot be determined. Most of the studies (e.g., Kellogg and Charnes, 2000, Perlitz, Peske and Schrank, 1999) use future cash flows of the R&D project as the proxy for the underlying asset. However, the future cash flows would largely depend on the probability of success of the drug. A successfully tested drug may not be successful in the market. Myers and Howe (1997) have shown that a drug reaching the market may fall into one of five quality categories: (a) dog; (b) below average; (c) average; (d) above average, or (e) breakthrough. The revenues associated with each quality category are highly skewed and the variance can be as high as 95 per cent (between breakthrough and dog qualities). Thus, estimating the underlying asset value for a researched drug could be very complex.

### Exercise Price

Exercise price may be known (e.g., in case of fixed price stock option) or stochastic. The exercise price of an R&D project is not always known. In the present case, as both the compounds have entered the clinical phase, it is assumed that all the three phases of clinical trial will be carried out and hence the present value of R&D costs has been considered as the sunk cost. The exercise price of the option to commercialize the products after clinical trials is, therefore, the investment required launching the products.

### Time to Expiration

Like exercise price, the time to expiration can either be known or unknown. Competition may force early investment but a regulation may delay the time to maturity. Usually stock options have a comparably shorter time to maturity. But, real options have a longer maturity period. Since DRL has applied to FDA as well for patent registration, we assume that it will get FDA approval for 20 years patent period. Clinical trials may take 6-8 years (Table 4) and hence the time to expiration could be 6-8 years at the earliest. Thus, DRL will get only 12-14 years of patent life after the products are launched. We will not consider revenue post-patent period in our study. We assume here that DRL will not wait after successful completion of Phase III. The products will be launched immediately.

### Volatility (Risk)

Measuring the volatility of an R&D investment project is difficult because it is difficult to get historical volatility data. DRL's two compounds (DRF 1042 and DRF 1644) may have features which are not present in its existing anti-cancer drugs. Merck & Company of the US uses the historic volatility of a bio-technology index of related stocks, which are traded at NASDAQ (Nichols, 1994). Ideally, historical data of research companies focusing only on anti-cancer drugs would have been the desired

database to compute volatility. In the absence of such information, volatility of stock prices of pharmaceutical companies may be used as a weak surrogate (Damodaran, 2000). A few such conservative estimates of volatility for the R&D projects were 40 per cent to 60 per cent (Nichols, 1994); 26 per cent (Kellogg and Charnes, 2000); and 25 per cent (Perlitz, Peske and Schrank, 1999). We have assumed volatility (variance) of 35 per cent. In fact, the annualized volatility (standard deviation) on the basis of 60 monthly returns of DRL's shares in the BSE comes out to be around 6 per cent, which is equivalent to a variance of around 36 per cent.

### Convenience Yield

For a traded underlying asset, convenience yield is the annual dividend yield on traded asset (e.g., shares). For R&D projects, estimating an appropriate convenience yield is a difficult task. An investment project generates cash flows that are often not exactly known by time, frequency or amount (Perlitz, Peske and Schrank, 1999). For a pharmaceutical company evaluating an R&D project, convenience yield should indicate the estimated net revenue (net of expenses) that would have been lost due to not being able to market the drug after patent registration. It is argued that the potential for excess return exists only during the patent life of the drug and, therefore, competition will wipe out excess returns beyond the patent period. Hence, any delay in launching the drug by a year will cost the firm one year of patent protected excess returns (Damodaran, 2000). One crude way to estimate such cost of delay could be the reciprocal of unexpired patent period, i.e., 1/20 (first year), 1/19 (second year), etc. This method is based on the assumption that cash flows are evenly distributed over the patent period. But, as this is not the case in most of the situations, this method of estimating convenience yield has not been used in the present study. In case of DRL, the current cash operating margin (Table 3) is 25 per cent. If the expected future margin from patented two compounds is 30 per cent per annum (based on the author's assumption that DRL earns a cash operating margin of 30 per cent on oncology products), the excess return that DRL may lose in the clinical phase will be the difference between expected operating margin and current operating margin. This method would give us a cost of delay (or convenience yield) of 5 per cent per annum for DRL.

Necessary input parameters for computing real options value of DRL's two anti-cancer compounds are given in Table 6. The following are some important points with regard to Table 6:

- R&D costs as reported by the US drug companies are always higher due to the following reasons: (a) The cost of failures is included in R&D costs of a successful compound. For example, if a company spends $1 billion in a year and develops two molecules with therapeutic quality, R&D costs per molecule are shown as $500 million. (b) Even opportunity cost (cost of capital) is included in the estimate. As no Indian company has so far developed a new researched drug indigenously, it is difficult to find the R&D cost of developing a drug in India. An estimate has shown that it could be as low as 20 per cent to 30 per cent of cost in the US. An analyst with Indiainfoline.com has communicated this information to the author.
- As per the *RBI Bulletin* (May, 2001, Table 27A, Page S470), the yield to maturity (YTM) of 6-8-year dated Government of India (GOI) securities, as traded on 31 March, 2001, is 9.98 per cent per annum on an average. This has been used as risk-free rate for estimation of cost of equity because the maturity of the securities matches with the time to expiry.
- The current market share of DRL in domestic anti-cancer market is around 22 per cent for three drugs. Hence, it is assumed that the two new compounds would capture 15 per cent of the domestic anti-cancer market. The domestic market share has been kept constant for the purpose of valuations.
- Conversion rate $1=Rs 47.

Table 7 shows real options value of two anti-cancer compounds of DRL under different scenarios. One striking feature of the table is that as time to expiry increases, values of options (and also NPV) fall (and do not rise). This is contrary to standard real options results where value of a call option is positively linked to expiration period. The reason for such a decrease in real options value (with the increase in time to expiration) is that as time to exercise is delayed, the unexpired patent period declines. As we have only considered cash flows during patent period, underlying value of R&D investment is used for 14 years (when t = 6), 13 years (when t = 7), and 12 years (when t = 8) respectively. We have assumed that the maximum period to complete clinical trials is eight years after which the option (of manufacturing the drugs) will be definitely exercised. DRL would have to bear the cost of delay (convenience

**Table 6: Parameters for Real Option Valuation**

| Input | Assumptions | Rationale/Source |
|---|---|---|
| Underlying asset | Present global market size of anti-cancer drugs=US$9.24 bn (1999) with 10 per cent annual growth rate. Present anti-cancer market size in India=Rs 700 million | Source: www.indiainfoline.com However, anti-cancer market is growing at 18 per cent per annum in India |
| Exercise price | Cost of launching the products is assumed to be Rs 900 million, which is equivalent to estimated cash flows in the first year of launch | Myers and Howe (1997) showed that in the very first year of product launch, the entire revenue is spent as marketing expenses. We have been optimistic |
| Time to expiry of option | 6-8 years | Table 5 |
| Volatility (Variance) | 35 per cent | — |
| R&D costs of developing a drug in India (sunk cost) | Rs 2,500 million per drug | Several estimates show cost of developing a drug in US as between $350 million-$500 million |
| Cash operating margin | 30 per cent | Present operating margin of DRL under price control environment is 25 per cent. |
| Effective tax rate | 30 per cent | — |
| Convenience yield | 5 per cent | — |
| Risk-free rate | 9.98 per cent | — |

yield) for the waiting period (6-8 years). It is intuitively assumed that if DRL fails to launch the drugs after eight years, it will lose the opportunity of capturing even 0.5 per cent of market share. If the global market share falls below 0.5 per cent (both the drugs), value of real options would be zero (i.e., options will not be exercised).

If global market share is assumed to be 0.5 per cent, real options show positive values. The traditional NPV method shows negative values. It implies that with an estimated global market share of 0.5 per cent for these anti-cancer drugs, NPV method would reject the current R&D investment. That is why traditionally it is believed that NPV of all R&D investments is nearly zero (Nichols, 1994; Myers and Howe, 1997). The results of Table 7 also imply one vital point. Unless DRL can envisage to capture 0.5 per cent of global anti-cancer market, it will be very difficult to recover the R&D investment. In fact, if the global market share for both the drugs falls below 0.4 per cent, the option value would be nil. So, attaining a reasonable market share is critical to exercise options. That is why, so far, not a single drug has been fully researched in India. Indian pharmaceutical companies have either acquired generic products or licensed out the compounds to multinational companies for clinical trial and commercialization. We have assumed that R&D of the two anti-cancer compounds will be solely done by DRL (it may use facilities of any research laboratory abroad) and also ultimately commercialized by DRL.

**Table 7: Real Option Value**

*(Rs in Million)*

| Global Market Share (%) | Time to Expiry (in Years) 6 | 7 | 8 |
|---|---|---|---|
| 0.5 | 1,773.14 (-1,164.20) | 1,474.59 (-1,664.52) | 1,187.66 (-2,099.58) |
| 1.0 | 8,357.85 (2,688.33) | 7,734.80 (1,685.51) | 7,140.12 (8,13.48) |

**Note:** Figures in the bracket indicate NPV.

Real options value of two compounds inflates the intrinsic value per share to as high as Rs 767 (Table 8). But the assumption of 1 per cent global market share is highly optimistic. The current market size of domestic anti-cancer drug market as compared to global market size is around 0.2 per cent. Therefore, imagining a market share of even 0.5 per cent for DRL is a tough task. In fact, so far, there is no drug in India which enjoys a global market share of 0.5 per cent in any therapeutic segment. Hence, it is clear that if DRL fails to capture the minimum market share, it would do better to license out the drugs (before completing clinical trials), suspend further investments, and rely on royalty payments. Licensing opportunities—whether to acquire or cast off a drug in development—are often key to increase the corporate value (Amram and Kulatilaka, 2000). But we have not considered these compound option features in the present study.

Incorporating real options value of anti-cancer drugs significantly improves the intrinsic value per share and such value accounts for around 50 per cent of market price. If we could have estimated the real options value of all pipeline research products, the shareholder value would perhaps have been closer to the prevailing market value. However, the calculations in the present study show that option value of the R&D initiatives would be close to zero, given the present level of global market share enjoyed by Indian pharmaceutical companies. This may imply that the capital market in India has a tendency to

**Table 8: Impact of Real Option Valuation on Shareholder Value (As of March 2001)**

*Value per Share (Rs)*

| Global Market Share (%) | Time to Expiry (in Years) 6 | 7 | 8 |
|---|---|---|---|
| 0.5 | 558.36 | 548.91 | 539.82 |
| 1.0 | 766.87 | 747.14 | 728.31 |
| Percentage of market price explained | | | |
| 0.5 | 43.35 | 42.62 | 41.91 |
| 1.0 | 59.54 | 58.01 | 56.55 |

**Note:** Value per share = [Static Value (Table 3)+Real Options Value (Table 7)] / Number of Shares.]

overreact to any positive announcement in the R&D efforts by pharmaceutical companies. But the study clearly shows the basic assumption behind the current R&D efforts of Indian pharmaceutical companies (viz, DRL and Ranbaxy) is that these drugs, if launched, would gain the critical mass. Otherwise, the real options analysis would draw same conclusions as the traditional DCF analysis.

## DECISION TREE APPROACH

The real options value suffers from two basic limitations:

- It is assumed that all clinical phases would be completed irrespective of the outcome of research and hence the R&D costs are considered as sunk costs.
- The probability of success in each stage is not considered.

Myers and Howe (1997) and Kellogg and Charnes(2000) argue that probability of success (and failure) after each stage of research can be estimated and hence the firm may decide to either continue or abandon the research effort after each stage. They also argue that the cost of capital (used for discounting the cash flows) would be different for development cash flows and commercialization cash flows. Normally, cash flows at development stage would be discounted at a lower rate (Table 9).

Both the anti-cancer compounds have completed pre-clinical trials and hence the R&D costs of Rs1050 million per drug (including FDA filing costs) is considered as sunk costs. R&D costs for clinical trial phases are assumed to be incurred evenly every year.

The Expected Net Present Value (ENPV) of the two anti-cancer drugs is a negative Rs.1,193 million (after deducting sunk cost) with the assumption that the drugs would be commercially launched after six years. The tree diagram is shown in Figure 2.

The decision tree approach incorporates the option of abandonment at each stage. However, the limitation of this approach is that continuous outcomes are "discretized" (Kellogg and Charnes, 2000). The sunk cost for both the proposed drugs is Rs 2,100 million (at the rate of Rs 1,050 million already spent per drug till Clinical I). Hence, the ENPV (after deducting sunk cost for two drugs) is negative. The decision tree approach fails to capture the value of options to launch a researched drug. Of course, the above result is more close to the findings of Myers and Howe (1997). The real options framework found a positive option value at global market share of 0.5 per cent for both the drugs.

## CONCLUSION

Pharmaceutical companies face a peculiar uncertain business environment. Roughly, one out of 10,000 explored chemicals becomes a prescription drug (Nichols, 1994) and only 30 per cent of drugs succeed in recovering their costs after commercialization. The above analysis of DRL has been done with an assumption that both the compounds would fall under the category of "successful

**Table 9: Parameters for Valuation under Decision Tree Approach**

| R&D Stages | Duration of Each Stage (Year) | Proportionate Costs (%) | R&D Costs per Drug (Rs Million) | Probability of Success |
|---|---|---|---|---|
| Discovery | 1 | 5 | 125 | 0.60 |
| Pre-clinical | 3 | 30 | 750 | 0.90 |
| FDA/Drug control filing for NDA | 3 | 7 | 175 | 0.75 |
| Clinical-Phase I | 1 | 6 | 150 | 0.75 |
| Clinical-Phase II | 2 | 14 | 350 | 0.50 |
| Clinical-Phase III | 3 | 38 | 950 | 0.85 |
| Cost of capital for R&D cash flows (%) | 12 | | | |
| Cost of capital for commercial cash flows (%) | 15 | | | |

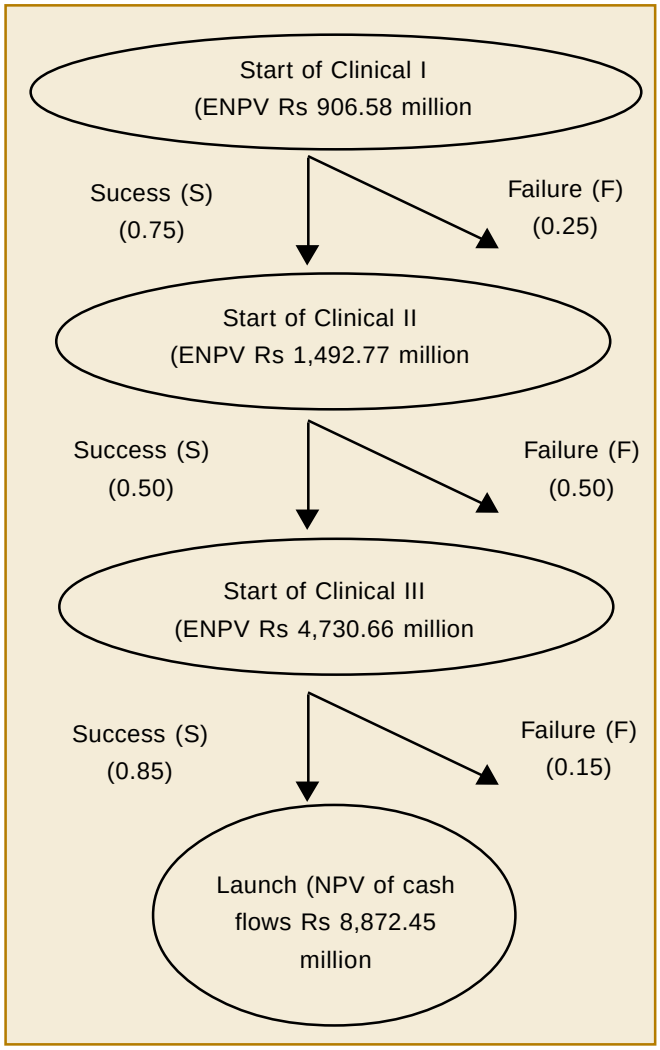
**Note:** Myers and Howe (1997) used a 3 per cent differential in discounting factor for R&D and commercial cash flows. Cash flows (R&D expenses) during R&D phases are more certain than cash flows after the launch of the successful drug. Hence, commercial cash flows are discounted with the nominal cost of capital of DRL for the year 2000-2001 and R&D cash flows are discounted at a lower rate of 12 per cent.

**Source:** Adapted from Kellogg and Charnes (2000), Table 1, p 79.

drugs." The option to abandon the research at any stage (and licensing out the drug) has not been considered. The abandonment option may increase the value of real options. For example, DRL has recently announced a multi-million dollar licensing deal for an anti-diabetes molecule with Swiss multinational Novartis AG. DRL is to receive payments of about $55 million over a period of time during the process of research. The study has shown that the underlying value of R&D investments is best recognized in option pricing model. The traditional NPV method fails to capture the underlying value. Another noteworthy finding of this study is that the present value of R&D is highly dependent on the expectation of achieving a critical mass in terms of global market share. R&D efforts are costly exercises. The Indian market for any high-investment research drug is comparatively small. Therefore, the success of a complete R&D- driven drug depends on its ability to capture global market. That perhaps explains why most of the Indian pharmaceutical companies have not completed the research and preferred to sell the research at molecule stage.

In reality, there are different stages of R&D investments (Table 4). So the value of R&D investments of a pharmaceutical company can ideally be captured with compound option model (Geske, 1979). But, the present study has not considered the compound options feature. It is true that application of any real options model requires more detailed information and assumptions. The results of the present study may improve with the availability of more information. It is also to be noted that regulation in drug discovery process reduces the value of options. Finally, a word of caution is necessary. The decisions taken on the basis of real options analysis may go notoriously wrong if the underlying assumptions are not meticulously designed. The model risk is very high.

**Figure 2: The Decision Tree**




**Note:** The NPV of cash flow at the final node "Launch" is based on 14-year cash flow projections with the global market share of 0.5 per cent for two drugs and growth rate of 10 per cent for exports and 18 per cent for domestic sales. The expected NPV (ENPV) at node "Start of Clinical III" is computed as below:
ENPV=Probability of success (0.85)* Rs 8,872.45 million/ (1+0.15) ^3-Probability of failure (0.15)*(950*2/3)*annuity factor (12%, 3 years) = Rs 4730.66 million.
Similarly, ENPV values for other nodes are computed.

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*We are now in the third stage of the industrial revolution. The first involved machines which extended human muscle; the second used machines to extend the human nervous system (radio, television, telephones); the third is now utilizing machines which extend the human mind—computers. About half of all service workers (43 per cent of the labor force by 2000) will be involved in collecting, analyzing, synthesizing, structuring, storing, or retrieving information... By 1995, 80 per cent of all management will be "knowledge workers."*

*Owen Davies*