Navigating through a Biotech Valuation
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What is a biotechnology company really worth? This question is often faced by corporations, investors, and bankers alike who may be putting their capital at risk in a biotechnology company. Unfortunately, there is no definitive answer to the question; no standard valuation methodology can be applied universally in order to determine value. Additionally, each available approach involves assumptions compounded by additional assumptions. More often than not, there is no method to isolate any specific scenario and guarantee, or even state with a reasonable degree of certainty, that the specific scenario or event will occur. For example, how can market share be predicted for a company when neither the product nor the market exist? Faced with such uncertainty, valuation of a biotech company appears to be a challenging endeavor.

Yet it is still imperative that a value can be estimated within a reasonable range for practical purposes such as raising capital, negotiating strategic alliances and joint venture agreements, investment decisions, and licensing strategies. Investors need to benchmark the company against other companies, to evaluate whether the market’s valuation for biotech companies are efficient or not.

There are difficulties faced in valuing most technology companies. The fair value of the company is typically driven by the value of the company’s intellectual property. For many high tech companies, the value of their tangible assets are minimal in comparison to their intangible assets, to which their returns can primarily be attributed. This difficulty is magnified in biotech companies, where a company’s ability to convert its intellectual property into a revenue stream is subject to strict government regulations and a lengthy approval process. Before proceeding with valuation, it is imperative that the unique features of a biotech company are understood so that the valuation method or methods are structured appropriately.

Unique Industry Factors
Companies in the biotech industry are characterized by many unique features which add significant complexity to biotech valuation and which impact the results. It is essential that those performing a biotech valuation assess the impact that these factors have on the company being valued to ensure that the valuation model selected is appropriate, as well as to determine the appropriate level of confidence that can be placed in the results derived from the model used. This is especially true for biotech companies which may not have any products on the market at the time of valuation. Once a product is marketed, the revenues and costs and product potential can be estimated with comparative ease. But, given the long time period between idea inception, regulatory approval and product marketing as well as the small number of ideas that ultimately result in a marketable product, this is rarely the valuation problem that will be presented. Significant uncertainty exists about whether the company will ever market a product.

One of the first things which should be appraised in a valuation is the company’s product pipeline, which is (1) the number of products that a company is developing and (2) the stage of development of those products. A company whose success or failure is entirely dependent on one product has a higher associated risk than a company which is developing several products. For example, in the drug development and approval process, only one in five thousand compounds that enter preclinical testing make it to human testing, and then only one in five are approved. Of those products which are approved, few biotechnology products which reach the market generate sufficient return to cover their cost. The stage of development for a company’s products is also critical. It will help the appraiser in estimating both the length of time before a product can be marketed and the likelihood that the product will even reach the market.

Another important issue to consider when valuing biotech companies is the burn rate. This refers to the level and rate of expenditures required for research and development (R&D) of the product. Comparing a company’s burn rate to its cash on hand and funds otherwise available is an important exercise when assessing risk. The Survival Index measures the relationship between cash on hand and net burn rate. Small companies have the smallest Survival Index, averaging enough cash on hand to cover only 13 months of research and development. See Exhibit 1, which shows monthly burn rates and survival indices by size and/or status of company. A company needs to have access to sufficient capital resources in order to sustain the significant levels of R&D required before a product will make it to market. Over 60 percent of therapeutic drugs currently on the market required in excess of $100 million in development costs. A company might obtain these funds through private investments, public offerings, loans, and alliances with larger companies who are willing to invest in their products and ideas.

Partnerships and strategic alliances have assumed an important role in the success of many start-up biotech companies, and therefore positively affect value. Very few companies have sufficient cash available to last more than five years. In fact, 33 percent of biotech companies have less than one year’s cash requirements on hand and over 50 percent of biotech companies have less than 2 years cash on hand. See Exhibit 2. Understandably, there is a great impetus for startup biotech companies to find venture capital, often in the form of a partner, to survive the development process. The biotech companies gain access to enormous pools of capital through the partnership arrangement in order to maintain their development efforts. The partners, often established pharmaceutical companies, are able to benefit from the knowledge transfer by obtaining marketing and manufacturing rights to products developed by their biotech partners. They might also share in the biotech company’s rights to the intellectual property itself.

While access to capital and improved chances for success are aspects of a partnership arrangement which increase value, another important aspect of these arrangements must be considered. In a strategic relationship, how are the rights shared between the parties? This sharing arrangement will impact the

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value of the biotech company, because different rights have different associated values. For example, the marketing and manufacturing rights mentioned above can be very valuable. If these have been given to a partner, the value of the biotech company has been reduced. It is important to determine if the biotech company has obtained comparable value in return through means such as invested capital or licensing fees.

Manufacturing, marketing and distribution capabilities impact value because they determine whether and how quickly a product can generate desired levels of revenue once it reaches the market. The existence of products is not sufficient to sustain value. The company has to be able to sell the product in a quantity and at a price to recover their investment and generate returns. This requires that they can manufacture the product in sufficient quantities and at reasonable cost (or arrange for its manufacture), create demand for the product, and then get the product into the hands of the public. This stage of the process also requires a significant amount of capital, something that many startup biotech companies do not have, especially after having just completed the lengthy development and cash draining process. So then one must determine the existence and availability of financing alternatives. This is where strategic alliances once more assume importance.

Protection of intellectual property is also an important element of valuation. Valuation requires some estimates on the future revenue generated by the product, and often these revenue forecasts are worldwide. Yet protection of intellectual property rights is difficult and expensive, especially on a global scale. “Pirating” means that the product will not reach the entire market, that there will be competing products which can steal both market share and profits. Even in the United States, where there are strict patent laws and available forums for protection, infringement of intellectual property rights occurs frequently, as evidenced by the growing amount of related litigation. As protection of intellectual property improves, the risk factor associated with revenue streams can be lowered which leads to greater value.

One feature of the biotech industry which makes valuation so complex is the product life cycle. A product has two distinct life cycles, (1) the development life cycle and (2) the product life cycle. The development life cycle is very long, on average ranging anywhere from 16 to 20 years. See Exhibit 3 which shows the typical number of years associated with the various stages within the development cycle. Exhibit 4 describes the activities occurring at each of the various stages. During this cycle no revenue is generated. The product life cycle begins once the product reaches the market. This is when a return on the investment finally takes place. The anticipated length of the product life cycle (the revenue generation phase) obviously affects value. This can be a fairly short time in contrast to the long development life cycle, sometimes lasting only a few years despite the fact that almost two decades of a government authorized monopoly is granted through patents. This is because the market is continuously refreshed with new or improved products that will compete with the subject product. If a market is perceived to be lucrative, development efforts will be targeted at that market and another product will likely be introduced and may assume market leadership.

The uncertainty of the biotechnology industry is compounded by the impact of changing regulations and government policies. Changing regulations can affect the length of time for a product to reach the market, and whether or not the product is granted approval. Changes in health care policies can have a major impact on product pricing and market size. As an extreme example, failure of insurance companies to reimburse expenses for certain drugs could potentially eliminate an entire market.

**Dealing with Uncertainty**

All of the unique features of the biotech industry discussed above have one factor in common, they all affect risk. As with any valuation, there is a defined relationship between risk and value. Greater risk associated with revenue and profit translates into less value today. Numerous questions exist which are impossible to answer with certainty. **Will the product work? Will the product be approved? Will there be...**

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5 PhRMA; “The Contribution of Pharmaceutical Companies”. 
a market for the product? How long will it take to get the product to market? Will the regulatory process undergo change? How will the market change during a lengthy development and testing process? Can the company obtain the resources to survive over this time? Will the technology be valuable ten to twenty years in the future?

There are no definitive answers to these questions; only forecasts, estimates, projections and pure guesses. Assumptions must be made based on experience, historical data, research, marketing savvy and instinct. The reasonableness of these assumptions can be improved by: researching the historical performance (i.e. success rates) of the developer, the biotech company and the biotech’s partner, if any; assessing milestones achieved to date in development of the product and the product’s actual position in the development life cycle; considering historical industry ranges or averages for such things as likelihood of regulatory approval, length of time until regulatory approval, development costs, etc.; performing research related to the potential market (i.e., determining the number of individuals affected by the ailment/condition to be treated by the new product, determining existing treatment methods, etc.); assessing the commitment of the investors or partners to the project; and considering the specific characteristics of the company which impact these risks (i.e., whether the company has entered into a partnership or alliance which secures access to capital).

Once the unique features and risks faced by biotech companies have been identified and assessed, they must be quantified. From available information numerous estimates must be derived with respect to market size, price sensitivity, competing alternative products and other factors. The challenge is this: to be able to estimate earnings of a product, company and market for which no historical information is available.

**Valuation Methodologies**

There are a variety of methods which can be used for valuation. The method selected should be suitable for the specific company. For biotech valuation, three main approaches which are generally appropriate are: (1) discounted cash flow analyses, (2) Monte Carlo models, and (3) option pricing models. There is a benefit to performing more than one type of valuation, as the results can be compared against each other. If the results are divergent, the assumptions made in the models may require reevaluation.

**Discounted Cash Flow**

Performing a discounted cash flow is a traditional approach to valuation, where estimated future cash flows are multiplied by a discount factor in order to obtain a present value. First, revenue and revenue growth projections must be formed for the company based on product expectations. Revenue forecasts involve projections of potential market share which is dependent on availability of competing products, product pricing, insurance reimbursement for the product and acceptance in the market place. Remember that often no active market exists at the time of the valuation as no products may be offered at that time. For biotech products, there might be quick market penetration followed by a tapering off of the growth as the product meets price resistance and/or competitive resistance. In the typical product life cycle, the product plateaus as the product matures in the marketplace.

In a discounted cash flow analysis, time is very important factor. A reasonable estimate must be made for the timing of revenues. For the biotech industry, this involves estimating the time required to obtain product approval, to bring the product to market, and to penetrate the market. A general rule in discounted cash flow is that projections should not be further than ten years into the future, since time magnifies uncertainty. This may not be feasible for valuing a biotech company, when it might be more than ten years before the product can be marketed.
After projecting revenues, the next step is to estimate expenses in order to project margins and incremental profits. Again, this is a complex process for biotech companies, as margins are dependent on the assumptions as to the availability of product substitutes more than ten years in the future. Margins are also dependent on the manufacturing, marketing, and distribution arrangements, for which there is no historical information on which to base an estimate.

The next step in performing a discounted cash flow analysis is to determine an appropriate discount rate which is driven by an evaluation of the company and product risk. The discount rate for biotech companies may reach as much as 25 percent to 50 percent, depending on the circumstances. While this might appear high, it is appropriate given the level of risk faced associated with biotech companies. The discount rate can be adjusted, based on milestones events which have been achieved at the time of the valuation. A discount rate of 25 percent might be appropriate for a company with a product in advanced clinical trials since there is less time to market, more information available on the product, and thus lower risk. A discount rate at the high end of the range (i.e., 50 percent) may be more appropriate when a company’s product is only beginning clinical trials since little information is available and the time to market is greater, meaning higher levels of risk.

Monte Carlo Simulation

Discounted cash flow analyses can be limited, since any specific method can only consider one set of assumptions at a time. With so many uncertainties associated with biotech companies, a discounted cash flow approach might be too confining. A flexible approach may be more suitable. Monte Carlo simulation, which is a tool for considering all possible combinations of events, is a method for determining the probability of certain outcomes and their related values.

In this simulation, potential payoffs are analyzed based on the statistical probability of certain outcomes. Ranges of estimates are determined for the various factors that affect value, including: market size, capital expenditures, product pricing, manufacturing rights, economic environment, time to market, existence of market, etc. After the significant variables have been identified, the probability distributions for output variables must be determined. A computer simulation is then used to predict results based on simultaneous changes in the variables.

On a cautionary note, the results of the simulation must be critically evaluated for reasonableness. The use of probability distributions and computer simulations causes this approach to appear to be very scientific. Although there are some distinct benefits to using this approach, common sense and experience must be used in evaluating the results since the method still involves a great degree of subjectivity. The assumptions regarding the probability and the significance of the variables are still subjective, and if the assumptions are not reasonable the results are meaningless.

Option Pricing Models

Option pricing models have gained strong acceptance as appropriate for use in situations of uncertainty. These models are valuable in the biotech industry, which is faced with uncertainty (as discussed above, where the size and profitability of future markets are unknown, sales will not commence for several years, there is an uneven distribution of returns, and there is overwhelming upside potential).

The most common option pricing model is Black-Sholes, which can generate a value from a continuum of possible outcomes, and can be modified to value a biotech company. The exercise price is the capital investment required. Duration would be the time until the product can reach the market. The standard deviation of stock returns for typical biotechnology stocks can be used as a measure of project volatility.
Option pricing models were scarcely used a decade ago, few were familiar with what they were or how to apply them. But these models have increased in popularity as business schools have incorporated them into their curriculum and emphasized the value of these methods to their students who graduate and join corporations.

Conclusion

Now that we have identified the unique features and tools of biotech valuation, are we any closer to being able to value a biotech company? It remains a complex exercise, somewhere between science and art. It requires the ability to navigate a course through unfamiliar territory, the distant future, often without the benefit of much history or experience. It involves understanding the industry, the company and the products. In addition to the information gathered, experience in biotech valuations is essential in distilling the information into reasonable assumptions which can be used in valuation models.

Use of a financial model is critical for assessing the value of a biotech company. These models must be tailored to reflect the unique features and risks associated with the biotech industry. A model should consider such things as: the number of products a company is developing, the stage of development of those products (including an assessment of any available information related to the likelihood of success of the product and an estimate of the timing that the product will reach the market), the company’s burn rate, the company’s cash on hand and/or access to capital (including partnerships or strategic alliances), the company’s ability to manufacture, market and distribute the products. Additionally, assessments must be made about events to occur in the future, including the potential market size, the length of the product life cycle, the likelihood and timing of competing products being introduced into the marketplace and changing government regulations related both to product approval and to protection of intellectual property.

For the future, increasing flexibility of models will improve the accuracy of biotech valuations. Just as use of discounted cash flow has become commonplace, alternative valuation methods such as Monte Carlo simulations and option pricing models may become the norm as appraisers gain familiarity and comfort with them.

References


PhRMA; “The Contribution of Pharmaceutical Companies.”


Recombinant Capital.