

Approaches to Life Science Evaluation

Author: Tim Moser, Industry Partnering Expert, EATRIS-ERIC

In November 2014, the California orphan disease biotech firm BioMarin <u>paid \$680 million</u> <u>upfront</u> to purchase Prosensa, a Netherlands-based specialist in RNA therapeutics for rare diseases. Prosensa had just completed a pivotal Phase 3 study in Duchenne Muscular Dystophy, which failed to demonstrate that its drug induced significant improvement for trial subjects, as measured by a walking test. Sadly for the patients and their families, this particular biotech story lacked a happy ending; despite additional efforts to repackage the clinical trial evidence for FDA review, and despite substantial lobbying by patient advocacy groups, the drug was not approved. Less than two years after the acquisition, BioMarin was left with nothing to show for their substantial investment and discontinued all further development of Prosensa drugs.

This brings to mind questions about how accurately even a large, sophisticated company can determine the value of a biotechnology asset. Why would they pay such a huge price to acquire a seemingly failed drug? Aren't there sound methods to assess value and determine fair prices for new drugs and diagnostics that are close to reaching patients or even those that are in earlier stages of development? How can so many biotech companies be acquired, or make their stock market debuts, only to see their initial value either appreciate or decline hugely in the short term?

Much of the difficulty of valuation in biotech comes down to underlying complexity in biotechnology itself. Until it's known that a drug or diagnostic works in its intended patient population, until that can be demonstrated to a regulatory body <u>and</u> until the owners are able to derive expected financial outcomes based upon a successful market launch, all of biotech valuation can be viewed by more skeptical observers as imprecise guesswork.

This is not to say that the biotech and pharma industry lacks methods for attempting to value what it produces. A common situation in modern drug development is that the party who discovers or invents the drug or diagnostic is not the party that ultimately brings the technology through late stage development, and the financial investments reflect the risk and benefit borne by parties at each stage. Under this modern development scenario, each successive stage requires a 'project' financial value to be calculated in order for sufficient investment to be made that both rewards the prior investors for their efforts, as well as providing enough capital to adequately fund the next stage of development. Between each individual stage, it's possible that development is legally handed off from one form of investor to the next, in the form of a contractual transaction like licensing or outright acquisition, where some sort of valuation is required. Like any other form of investment, each party may want to know: (1) what they will need to invest; (2) what may be their probability of success; and (3) what they will earn if their hard scientific work is successful.

Investment requirements and the probabilities of conversion into marketed products have been illustrated in a chart produced by Ralph Villiger, an expert in valuation of biotechnology assets. This chart provides numerical illustration of the number of projects (compounds, molecules, antibodies) that would need to feed into a pipeline in order to obtain one marketed drug at the end of the cycle. Each successive stage not only requires more investments to develop, but also sees the increased value of the asset. Furthermore, this also provides a visual example of why a drug costs anywhere from \$1 billion to \$5 billion to bring to market; in actuality, a pharma or biotech company is investing in 500 - 1000 early stage projects to obtain one marketed drug. Mr. Villiger derives a figure of \$1.7 billion:



Even earlier in academic development, there are examples of technology development where various types of valuation may be directly or indirectly required:

- applications for public research financing for further development of basic inventions to diagnose or treat a disease, where disease prevalence and incidence estimates provides useful information toward predicting the economic and public health benefit of the invention potentially being funded;
- proof-of-concept funding to develop a technology that may be in process of patenting, or just beyond;
- licensing and spinoff agreements that attempt to capture the value of inventions being developed in fair terms based upon valuation of the underlying asset;
- shareholder agreements that assign shares in spinoff companies to the company founders, in recognition of the underlying perceived value of the new technology and therefore the company;
- assignment agreements which transfer the ownership rights for intellectual property;
- acquisition agreements for companies being sold from one set of founders/owners to another party.

Life science intellectual property is arguably one of the most difficult assets for which to accurately derive financial value, due to a number of unknown - and unknowable - factors. Nonetheless, there are some basic methods for determining value of the new ideas:

<u>Net Present Value</u>: A valuation method which uses cash flows - investments into a project and financial income out of a project - which are weighted on the basis of how far in the future they occur, and using a weighting variable that reflects inflation and opportunity cost of capital. The attraction to using net present value is that it ultimately produces one present-day financial figure, which is considered to be a worthwhile sign to undertake if positive. This method is amongst the most widely used valuation and decision support calculations in finance.

<u>Decision Tree</u>: Valuation using decision trees calculates values based upon probabilities of outcome of individual stages within the investment project, which can especially useful for the sorts of staged development projects seen in biotech and drug development.

Internal Rate of Return: This method is used to compare rates of return amongst multiple projects, where the comparison metric is an annualized return rate. A major disadvantage of this method is that, due to mathematical reasons, each time a project switches between positive to negative, it adds an additional rate of return. For long projects that may generate returns in some years but require investments in others, it can be difficult to determine which rate to use.

Other methods of various levels of financial complexity exist, but for an initial assistance in determining a valuation for your innovations, your local technology transfer office may be your first contact point. We at CORBEL Innovation Office are standing by for assistance if you have any further questions.

Keywords: valuation, project, investment, return, licensing, spinoff, acquisition

Experts in the field of life sciences valuation: <u>Avance</u> <u>Venture Valuation</u>