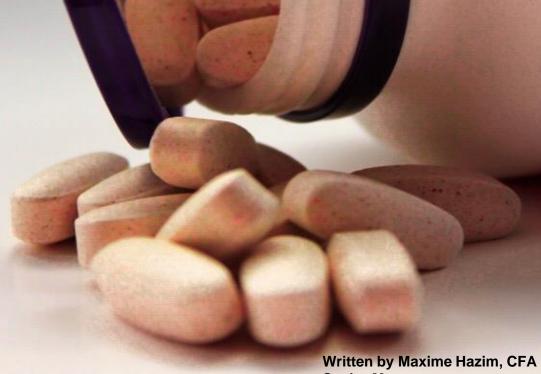




HOW TO EVALUATE A BIOTECH COMPANY?



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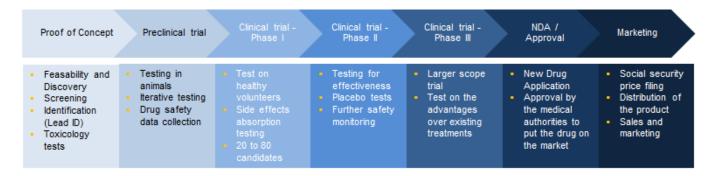
How to perform a biotech valuation?

A biotech is a company that engages in research and development (R&D) based on biological processes, organisms, or systems to manufacture products intended to improve the quality of human life. Unlike traditional pharmaceutical businesses, biotech companies' core business is, and in the most cases limited to, R&D.

The valuation of a biotechnology company (or biotech) cannot be performed in a conventional way. The lack of assets, revenues and earnings makes the application of the traditional valuation methods (DCF, Comparable multiples,...) quite difficult and irrelevant.

The drug development process

To understand the biotech environment, it is crucial to gain an understanding of the development stages of a biopharmaceutical product. The following figure shows these various stages.



The *proof of concept* phase is a feasibility phase where the concentration is on the discovery and identification of a non-toxic lead compound that can target a specified pathology.

The *preclinical trial* phase's objective is to verify the safety of the drug. The testing of the drug is done in animals at this stage. Once the preclinical trial succeeds, the drug can be filed for testing in a clinical trial.

In the *clinical trial phase I* (testing in humans) the number of candidates is relatively small and the testing is focused on healthy volunteers. The goal is to observe the side effects absorption of the drug by the human body. If phase I succeeds, the testing for effectiveness is done in the *clinical trial phase II*. Within this phase, placebo tests are done and further safety monitoring is performed. In the *clinical trial phase III*, a larger scope is tested. The focus is concentrated on the advantages of the drug being tested over the existing treatments.

If the results of the Phase III are a success, a new drug application ("NDA") is filed with the medical authorities in order to obtain the authorization for the drug to access the market.

The drug development and testing process can be long and presents high risks of failure at each stage. Investing in the drug development is hence long term and presents above average risk. The probability of reaching the market increases with the success of each phase and hence the value of the company appreciates with each success.

Biotech funding and cash flow generation

With their low revenues and high cash burning R&D costs, biotech companies almost always fund their activity with equity. The call out for venture capital and business angels is therefore very common.

A typical path of biotech companies is to develop the drug until it succeeds the Preclinical trial. It is starting this stage that bigger pharmaceutical companies start to find interest in acquiring the exploitation rights of the biotech companies' products. The exploitation rights acquisition is done via a patent licensing contract where the biotech company (the licensor) provides the rights of use and marketing of the drug being developed to the pharmaceutical group (the licensee). In compensation to the licensor, the licensee makes several forms of payments:

- Signing fee, also called the "initial payment", which helps the biotech company to recoup some of its investment,
- Milestone payments which are triggered by product or service development benchmarks, and they serve to compensate the licensor as the value of the licensed technology increases. Typical milestones include designation of a "lead compound", filing a new drug application (NDA), completing a clinical trial phase (Phase I, II and/or III), and first commercial sale. The amount of milestone payments differ, but should relate to the amount of investment required and the licensee's potential return on that investment in view of the increased value of the technology,
- Royalty payments which mainly apply once the drug has reached the market. Typical or standard royalty schemes may include minimum annual royalties and a percentage royalty on sales.

While the above items are the essential part of the revenues of a biotech company, the essential costs are R&D costs and preclinical and clinical trial costs.

The RNPV model as a valuation methodology

The most adapted method to take into account the characteristics of a biotech is the RNPV (Risk adjusted Net Present Value) model. This method combines the discounted cash flow model with the success probability of each phase.

The application of the method can be breakdown in 5 steps:

Step 1: Calculation of the discounted free cash flows. After calculating the free cash flows like in a DCF methodology, a discount rate should be applied. The discount rate corresponds in principle with the weighted average cost of capital (WACC) but in most case, as biotech companies are equity financed, the discount rate to be used is the cost of equity.

Cost of equity is determined by using the Capital Asset Pricing Model (CAPM) which is defined as follows:

$$K_E = R_F + (ERP \times \beta) + R_S$$

Where:

K_E = cost of equity capital
 R_F = risk-free rate of return
 ERP = Equity risk premium

β = Biotechnology beta (which can be estimated via listed comparable

companies or other industry benchmarks)
R_S = specific risk premium

Determining the cost of equity remains challenging especially when the company to be valued has a specific risk due to its size, its stock illiquidity, its market location, its field of activity, etc...

Step 2: Breaking down the business plan in scenarios with each scenario representing the failure of a given development phase and including the ultimate scenario of accessing the market

Step 3: Determination of the success rate (probability) for each development phase based on available trial statistics published in scientific journals (Nature,...)

Step 4: Calculation of the probability and the sum of discounted cash flows for each scenario

Step 5: Calculation of the probability weighted value of all scenarios

The following example shows how the RNPV method can be applied by using the calculated discounted cash flows and the success rates of the various development phases:

Success rates of the various development phases (example)



Discounted free cash flows			Proof of Concept		Preclinical phase	reclinical		Clinical Phase II	Clinical Phase III		NDA approval	Marketing termir			terminal
Scenario	Probability	value	2016	2017e	2018e		2020e	2021e	2022e	2023e	2024e	2025e	2026e	2027e	value
Failure of the Proof of concept phase	35,0%	-735	-383	-352											
Failure of the Preclinical phase	32,5%	-1 627	-383	-352	-892										
Failure of the clinical phase I	10,4%	-2 857	-383	-352	-892	-565	-665								
Failure of the clinical phase II	14,6%	12 687	-383	-352	-892	-565	15 679	-800							
Failure of the clinical phase III	2,4%	31 923	-383	-352	-892	-565	15 679	19 935	-500	-1000					
Failure of the NDA approval	1,0%	43 488	-383	-352	-892	-565	15 679	19 935	-500	10 565					
NDA approved and access to the market	4,1%	190 608	-383	-352	-892	-565	15 679	19 935	-500	10 565	11 597	12 740	13 506	14 272	95 005
Risk Adjusted Net Present Value	100,0%	9 832													

Specific valuation expertise for a specific sector

The valuation of a biotech company requires deep industry knowledge and reliable statistical studies. These studies should be discussed with the management before applying the RNPV model which allows evaluating the various molecules developed by the company.

For more information

Crowe HAF has developed an in depth expertise in biotech companies valuation. They performed valuation s in the framework of a major merger in the biotechnology sector in France.

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