Accelerating Innovation in Life Sciences

Intellectual Property Valuation in Biotechnology and Pharmaceuticals

WIPO

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Contents

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Abbreviations

BOPM	Binomial option pricing model
CF	Cystic fibrosis
DF	Discount factor
IP	Intellectual property
IRR	Internal rate of return
NPV	Net present value
rNPV	Rosk-adjusted net present value
USD	United States dollar

Key takeaways

Valuing intellectual property (IP) in the biotechnology and pharmaceutical sectors can be a daunting task, but understanding the key takeaways can simplify the process. Whether you are new to IP valuation or an experienced innovation management professional, the following key takeaways will guide you through the essentials. From valuation methods to market analysis, and risk evaluation to collaboration strategies, this list provides the crucial points to consider. With these in mind, you will have the knowledge and confidence to unlock the full potential of your biotechnology and pharmaceutical assets.

Key takeaways include:

Understand the purpose: Clarify the purpose of the IP valuation to be undertaken, whether it is for investment decisions, licensing agreements, fundraising or strategic planning.

Valuation methods: Familiarize yourself with the income-based and market-based valuation approaches, including discounted cash flow, risk-adjusted net present value (rNPV), market comparables and options-based thinking.

Market and competitive analysis: Conduct thorough market research and competitive analysis to assess the potential market size, growth opportunities, competitive landscape and barriers to entry.

IP protection: Recognize the importance of IP protection and understand how strong patents, trademarks, copyrights and trade secrets can enhance the value of biotechnology and pharmaceutical IP assets.

Development stage: Consider the development stage of the IP asset, as it influences the valuation. Early-stage assets often carry higher risks but may also have greater growth potential.

Clinical development and regulatory pathway: Evaluate the progress and potential risks associated with the clinical development and regulatory pathway. Understand the time, costs, and uncertainties involved in obtaining regulatory approvals.

Cash flow projections: Develop realistic cash flow projections based on a thorough understanding of the underlying risks, success rates, peak sales estimates, and market dynamics.

Risk assessment: Assess the key risks associated with the IP asset, including scientific, legal, regulatory, market and competitive risks. Quantify and incorporate these risks into the valuation model.

Expertise and team: Recognize the importance of the development team's expertise and track record. A strong team with relevant experience increases confidence in the project's success and impacts the IP's valuation.

Collaborations and partnerships: Consider the value of collaborations, partnerships and licensing agreements. Evaluate the potential for additional resources, expertise, market access and strategic alliances.

Exit strategies: Evaluate potential exit strategies for investors or the IP holder, such as acquisitions, licensing-out or public offerings. Understand the options available and their potential impact on the IP's value.

Regulatory and legal considerations: Recognize the legal and regulatory constraints that may impact the valuation process. Ensure compliance with relevant laws and regulations governing IP, licensing, data protection and confidentiality.

Continuous monitoring and updates: Regularly reassess and update the valuation as new data and information become available. Monitor the project's progress and market dynamics to ensure the valuation remains accurate.

Sensitivity analysis: Conduct sensitivity analysis to assess the impact of key variables and assumptions on the valuation results. Identify the most influential factors and understand their implications.

Expert input: Seek input from domain experts, experienced professionals or consultants to validate and refine the valuation analysis. Their expertise can provide valuable insights and enhance the credibility of the results.

Communicate effectively: Clearly communicate the valuation findings, assumptions, and limitations to stakeholders. Use visual aids and concise language to convey complex concepts to non-experts.

Strategic decision-making: Use the valuation results to inform strategic decision-making, resource allocation, licensing agreements, and further development strategies. Understand the risk-reward trade-offs associated with different investment choices.

The key takeaways presented here provide a glimpse into the important considerations and factors that impact the valuation process. However, to truly grasp the intricacies and develop a comprehensive understanding, we encourage you to dive into our guidebook. You will find detailed explanations, practical examples, and valuable insights that will equip you with the knowledge and tools needed to navigate the world of IP valuation with confidence.

Introduction

This chapter frames the unique valuation challenges facing biotechnology and pharmaceutical innovations, where assets often progress through long, uncertain development pathways. It highlights how clinical stages (pre clinical, Phase I, II, III, and regulatory approval_ fundamentally influence the level of uncertainty and the credibility of valuation inputs. The introduction sets expectations that biotech valuation demands both rigor and flexibility, balancing quantitative methods with assumptions informed by sector expertise.

This publication is an integral part of the World Intellectual Property Organization (WIPO) Series on Intellectual Property Valuation initiated by the Intellectual Property (IP) for Innovators Department.

WIPO has commissioned the development of this work to support life sciences innovation professionals and technology transfer managers in research-intensive universities, startups and spinouts, as well as small- and medium-sized businesses. It aims to facilitate the valuation of early-stage IP in biotechnology and pharmaceutical companies with a focus on professionals operating in early-stage innovation ecosystems. It is assumed that the techniques and approaches described herein are well understood by valuation professionals in well-established biotechnology and pharmaceutical organizations.

We navigate the process of translating early-stage IP (discovery) through clinical trials, regulatory approval and into the market, and discuss how the development process impacts the risk profile of IP and, therefore, the evolution of IP value along the way. We underpin theoretical concepts with a case study and worked examples to demonstrate how the valuation methods work in practice, and focs on how the pharrmaceutical and biotechnology sectors differ from other industries in terms of the development timeline, the structure, and the binary nature of outcomes.

The main focus is on valuation approaches used in practice in the pharmaceutical and biotechnology sectors, namely income-based approaches and the comparables method.

The guide is designed to be a helpful guide for innovation professionals who seek a fundamental understanding of the approaches used in valuating IP in the biotechnology and pharmaceutical sector. We encourage the reader to master the techniques described and seek professional advisory support when developing valuation models for IP under their management.

Introduction to biotechnology and pharmaceuticals

Biotechnology may be defined as the integrated use of biochemistry, microbiology and engineering sciences to achieve technological (industrial) application of the capabilities

of microorganisms, cultured tissue cells and parts thereof (Table 1).[1] Essentially, it is the technological application that uses living organisms and their derivatives to create products and processes for a specific use.[2]

Products emerging from this field are very diverse, from yeast used in baking and penicillin as an antibiotic, to using enzymes to clean up oil spills. Pharmaceuticals can be chemically synthesized (synthetic products), formed by chemical reactions following a set of biological fermentation and extraction processes (semi-synthetic products, such as some antibiotics). Collectively, these products are called *small molecule products*. Or, pharmaceuticals can be manufactured through fermentation or other processes that are fundamentally biological in nature rather than chemical (biological products). These biologicals typically have a molecular size that is many times that of the synthesized organic molecules (hence the use of the term small molecule) and are produced via a variety of distinct approaches. Cell and gene therapy products are frequently referred to as advanced therapeutic medicinal products. Within this guide, no distinction will be made between biotechnology and pharmaceutical products or industries, as valuation approaches are the same within these broad life sciences domains.

Table 1. Disciplines and application areas in biotechnology (non-exhaustive)

Biotechnology field	Disciplines	Application areas
Bioengineering and bioprocessing	Molecular biology Systems and synthetic biology Process engineering Biochemical engineering Applied microbiology	Chemicals (fine, bulk, cosmetics, etc.) Biofuels Medical devices Pharmaceuticals Bio-catalysis Food and drink processing Plant biotechnology
Biobased materials	Bioprocess engineering Enzyme technology (synthesis, functionalisation, bio adaptation) Polymer chemistry Bio recycling Bio nanotechnology	Textile and fibre processing - renewable materials - biomedical (resorbable implants, gauzes) - biobased plastics
Microbial biotechnology	Genetics Genomics Proteomics Immunology Pathogenesis Structural biology Bioinformatics	Pharmaceuticals Agricultural Environmental Medical technologies
Plant, Agriculture & food	Enzymatic action Fermentation Yield management Botany Reproduction	Crop fortification Plant disease mgt. Aquaculture Pest resistance Biofuels
Environmental biotechnology	Biowaste Bio refining Water sanitation CO2 fixation Bioremediation	Waste management Biodegradables Renewable chemicals

Source: Author

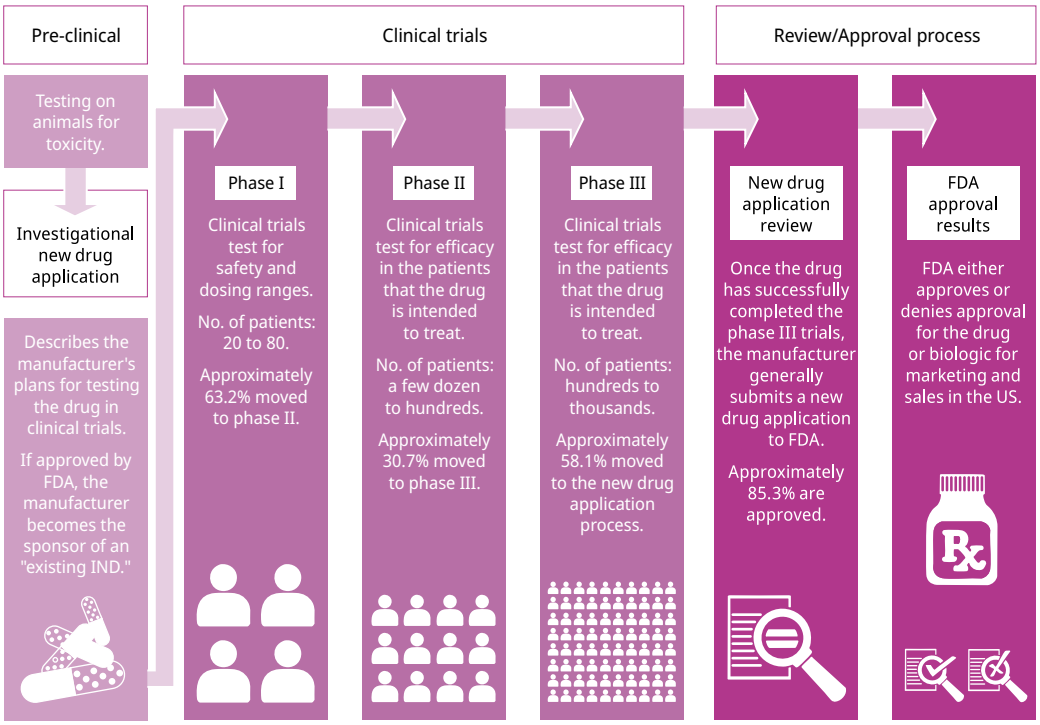
How the biotechnology sector differs from others

Compared to other sectors, the drug development process follows a well-established structure as shown in Figure 1. Briefly, the process begins at discovery, where thousands of compounds are investigated as potential drug candidates. Those that meet the criteria for further development enter pre-clinical studies in which in vitro and in vivo investigations are

1 European Federation of Biotechnology, 1981.
2 Convention on Biological Diversity, United Nations, 1992.

conducted. Successful candidates enter clinical trials, characterized by phase I trials focused on safety and dosage, after which successful candidates enter phase II trials which test for efficacy in a small group of patients. Phase II trials lead to phase III, which similarly test for efficacy, but at a large scale, often involving thousands of patients. The drug candidate is then submitted for regulatory review which requires the examination of submitted clinical trial data. The focus at this stage is on the safety and effectiveness of the drug. The applicant will be required to work on developing prescribing information (labeling). After review, an approval decision is made by regulators. Once the drug has been approved for the market, it undergoes a post-market safety review focused on the long-term safety of drugs. Any changes to formulation, dosage or labeling and the development of new uses or forms (tablet, oral, injectable) are subject to new applications to the regulator(s) and require additional approvals. Regulators also ensure that advertising is aligned with the drug's intended purpose.

Figure 1. The drug development process



Source: GAO analysis of FDA data and a 2016 collaborative study by the Biotechnology Innovation Organization, Biomedtracker and Amplion

In Figure 1, the regulatory process of the Food and Drug Administration (FDA), a drug that is yet to be approved for general use by regulators is known as an Investigational New Drug (IND). The analysis shown was conducted by the US-based Government Accountability Office (GAO). The drug development process from discovery to postapproval reviews can take up to 10 years or more depending on the indication. The drug under scrutiny can fail at any point in this process, which could cost billions of dollars depending on the clinical area and stage of development. Consequently, this binary nature of drug development presents a substantial risk compared to utilizing IP in other sectors where it is likely to:

- Undergo a shorter development process to market.
- Have more room to pivot – design around performance or functionality challenges.
- Undergo a less onerous regulatory approval process, concerning data submission requirements, cost and process.

As a result, the risk profile in biotechnology necessitates careful consideration when valuing IP in this sector. In addition, the long development for biotechnology IP are often beyond the conventional return on investment timeline expectations for capital providers. For many investors, a three-to-seven-year period is typical, beyond which they would prefer to exit or evaluate their investment. In addition, drug development incurs remarkably high capital expenditure, with the average prelaunch development costs ranging from USD 161 million to USD 4.54 billion across all therapeutic areas (Schlander *et al.,* 2021).

Intellectual property valuation methods in the biotechnology sector

Innovation professionals working in research-intensive universities, startups, spinouts or small- and medium-sized businesses understand the significance of valuing IP assets. IP valuation plays a crucial role in strategic decision-making, technology transfer, licensing, attracting investments and overall IP commercialization.

In this comprehensive guide, we will explore the most popular IP valuation methods tailored specifically for the biotechnology sector. Each valuation method offers a unique perspective on assessing the value of your IP assets, enabling you to make informed and strategic choices.

The valuation methods we will explore are the following:

- **Cost method –** The cost method estimates the value of an IP asset based on the costs incurred in its development. It provides a starting point by considering the investment made in research and development activities, clinical trials, regulatory filings and other related expenses.
- **Market approach –** The market approach determines the value of IP by comparing it to similar IP assets that have been recently sold or licensed. This method relies on market data and transactions to gauge the value of your IP in the current marketplace.
- **Income approach –** The income approach assesses the value of IP by estimating its future income-generating potential. It considers factors such as projected cash flows, expected revenues, licensing fees and royalty streams to determine the present value of the IP asset.
- **Real options method –** The real options method acknowledges the flexibility and potential future opportunities associated with IP assets. It allows you to value the strategic choices and opportunities that may arise during the development and commercialization of your biotechnology IP. By considering the uncertainty and the ability to modify the project based on new information, the real options method provides a more comprehensive valuation.

Throughout this guide, we will delve into each of these valuation methods, providing detailed insights into their application, strengths, and limitations. By understanding and effectively utilizing these valuation techniques, you will gain a comprehensive toolkit to assess and maximize the value of your biotechnology IP assets.

Valuation professionals may complement their preferred valuation method with other methods to address any perceived gaps in their approach. For instance, outputs from the income-based approach may be complemented with the comparables method of IP value, to support negotiations between IP owners and potential licensees or investors, who favor one valuation approach over others. IP valuation should be defensible and easy to articulate to both internal teams and other stakeholders. The assumptions used in the valuation process must be data-driven and, wherever possible, draw from well-established industry parameters. For a more advanced discussion on IP valuation in life sciences, we recommend the practical guide by Bogdan and Villiger (2010).

Important context and assumptions in biotechnology IP valuation

Valuing IP in biotechnology and pharmaceuticals involves significant uncertainty, particularly at early stages (pre-clinical through Phase I). Due to high risks, uncertain clinical outcomes, and the speculative nature of future markets, early-stage biotech IP valuation relies extensively on expert assumptions, forward-looking scenarios and flexible methodologies. As technologies progress through later stages of clinical development (Phase II, III, and regulatory approval), uncertainty gradually diminishes, enabling more precise, quantitative valuation methods. Readers should recognize these inherent uncertainties early to better understand and apply the methods described in this guide

Alignment with international valuation standards

The International Valuation Standards Council (IVSC) actively promotes globally consistent, transparent, and robust valuation methods. These standards suit assets with well-defined markets, predictable cash flows, and sufficient historical or comparable data – conditions more typical in later-stage biotech IP (Phase III and beyond, and regulatory approval).

For early-stage biotech assets (pre-clinical and Phase I), valuation methods though still quantitative in structure, rely heavily on qualitative, speculative, or scenario-driven inputs due to limited data and high uncertainty. At this stage, while robust methods like risk-adjusted Net Present Value (rNPV) and Real Options are employed quantitatively, the underpinning assumptions (probability of success, market penetration and pricing) are predominantly derived qualitatively through expert opinion, scenarios and judgments.

As biotech IP matures (particularly Phase II onwards), valuations begin incorporating progressively stronger quantitative inputs such as clinical efficacy data, emerging market comparables anddefined regulatory timelines, thus improving alignment with IVSC standards. By Phase III and at regulatory approval stages, valuations typically adhere more closely to rigorous quantitative standards, given the availability of concrete, quantifiable data.

This guide complements the Intellectual Property Valuation Basics for Technology Transfer Professionals by explicitly focusing on biotech-specific valuation dynamics. Practitioners are encouraged to apply iterative valuation practices, beginning with speculative and expert-informed assumptions at early stages, and gradually transitioning to more quantitatively rigorous, IVSC-aligned methods as clarity and data availability increase. This structured progression provides credible, transparent valuations at every stage of biotech innovation.

1 The cost method

The cost method values biotech IP by estimating the investment required to reproduce or replace the innovation. While it offers a baseline in the absence of robust clinical or market data, it rarely captures the true commercial potential of assets given the high risks and intangible factors involved in development. The chapter positions the cost method as a limited but sometimes necessary tool, particularly in the earliest stages of research.

The cost method is one of the commonly used methods for IP valuation. This approach estimates the value of an IP asset by determining the costs incurred in developing it to its current status. This approach assumes that the value of the IP is equal to the sum of the costs invested in its creation to date.

To apply the cost method in the biotechnology and pharmaceutical sectors, innovation professionals typically consider the direct and indirect costs associated with IP development. Direct costs include expenses related to research and development activities such as laboratory supplies, equipment, personnel salaries, clinical trials, and IP and regulatory filings. Indirect costs include overhead expenses, administrative costs and other expenses incurred to support the development process.

By carefully documenting and tracking these costs throughout the development stages of the IP, innovation professionals can establish a comprehensive record of the financial investment made in the IP asset. This information forms the basis for the cost method valuation.

However, it is important to note that the cost method alone may have limitations when valuing IP in the biotechnology and pharmaceutical sectors. It does not directly consider the potential market demand, future cash flows or the commercial potential of the IP asset. Therefore, it may not capture the full value of the IP, especially in cases where the costs incurred do not align with the future earning potential of the technology.

That said, the cost method can be appropriate under certain circumstances, particularly when evaluating IP assets at later stages of development or when assessing the value of tangible assets associated with the IP. Valuable insights can be gained via the cost method, under certain circumstances, such as:

- **Early-stage IP –** In the initial stages of a biotechnology project, where substantial investments have been made in research, development and initial testing, the cost method can be useful. It helps capture the resources and expenses incurred to date, providing a baseline for assessing the IP's value. This approach acknowledges the time, effort and financial commitments required to reach the current stage of development.
- **Tangible assets –** It is particularly relevant when valuing IP assets that involve tangible components, such as laboratory equipment, manufacturing facilities or proprietary technologies. By considering the replacement or reproduction costs of these assets, the cost method can help determine their value within the broader IP valuation framework.
- **Internal decision-making –** The cost method is valuable for internal decision-making purposes, such as budgeting, resource allocation and project prioritization. It allows

biotechnology companies to assess the financial implications of their investments in research and development and make informed choices about resource allocation based on the costs incurred.

Considerations when using the cost method

In the field of biotechnology, it is important to recognize that spending money on research and development does not automatically guarantee the creation of valuable products. Even if a firm has made investments in research and development, the development of useful products may not have been fully realized, resulting in sunk costs. For instance, in the pharmaceutical industry, products that fail in clinical development have a minimal value despite the significant resources invested in advancing new chemical entities into clinical trials.

When using the cost method in IP valuation, it assumes that the development process has been effectively managed and efficient. To illustrate this, consider a scenario where three competing firms have developed a novel drug delivery technology and associated manufacturing processes for specialized dose forms. Each firm has spent varying amounts: USD 10 million, USD 40 million and USD 60 million, respectively. The value of the technology to a potential acquirer using the cost method can vary widely within this range. However, it is reasonable to consider a value towards the lower end of the range as a reflection of efficient development.

The cost method may be more applicable in cases where there is an outright acquisition of all rights to a compound asset or technology. However, when seeking a geographically restricted exclusive license or dealing with non-exclusive rights, it can be challenging to apportion costs effectively between different territories, leading to complexities in valuation. In negotiation practice, the cost method may sometimes serve as a psychological floor on the price, particularly when divesting all rights to a technology or product.

In general, it is more helpful to focus on the benefits that access to the technology can provide to the acquirer rather than solely considering the costs incurred by the developer. The income approach allows for the evaluation of these factors and provides a more comprehensive perspective in IP valuation.

The cost method should not be the sole method employed for IP valuation in the biotechnology sector. Given the high attrition rates and uncertainties associated with biotechnology projects, additional approaches, such as the market approach, income approach and real options method, should be considered to provide a more comprehensive and accurate assessment of IP value. The cost method can be used in conjunction with these methods to provide a holistic view of the IP's worth, considering factors beyond the costs incurred, such as market potential, competitive landscape and technological advancements.

2 The market approach

The market approach benchmarks value by referencing comparable biotech transactions, such as licensing deals, mergers, or acquisitions. Its strength lies in grounding valuations in real world data, but its usefulness is constrained by the scarcity of publicly available or truly comparable deals, especially for early stage assets. The chapter concludes that while powerful in later stages, the market approach must often be supplemented by other methods in biotech.

Imagine that you created a new type of apple that is purple yet tastes like pineapple. You would like to determine the price at which to sell your invention. You may go to your local fruit and vegetable market and find as many apple sellers as possible and determine how much they sell their apples for. At this point, you can then determine the average price of these apples and use that value as a proxy for the value of your new apple variety. This approach is the basis of the market approach to valuation. IP owners seek out recent relevant trade deals for IP comparable to their own in terms of maturity, application area, benefits and other features. They then use the values collated to determine a reasonable value for their IP.

The market approach can be used to value individual IP assets or entire companies. By understanding the importance of comparing recent relevant deals and extracting useful data, one can effectively utilize the market approach to value early-stage drug candidate assets. You are encouraged to consider the following factors when applying the market approach.

Importance of comparing recent relevant deals

Comparing recent relevant deals is essential because it provides real-world transactional data that reflects the value of similar assets. By examining deals that have recently taken place within the biotechnology industry, innovation professionals can gain valuable insights into market dynamics and investor expectations. These comparisons allow for a more accurate estimation of the value of their own early-stage drug candidates.

Types of deals to compare and sourcing of information

When employing the market approach, innovation professionals must focus on comparing deals that involve similar early-stage drug candidates. These deals can encompass a range of transactions, including licensing agreements, partnerships, acquisitions or investments in companies operating within comparable technologies or therapeutic areas. To source the necessary information, professionals can leverage their network contacts, such as venture capital providers, who often possess valuable data from their investment portfolios.

Furthermore, thorough research conducted by analysts can uncover publicly available information on recent relevant deals, which may include regulatory filings, industry reports, news articles and investor presentations. To ensure comprehensive data collection, IP valuators must cast a wide net, exploring various sources such as:

- **Industry surveys and publications:** Industry-specific surveys and publications, like the *Licensing Royalty Rates* by Battersby and Grimes, offer compiled licensing data from multiple sectors and are regularly updated.
- **Professional networks:** Collaborating with peers in the industry provides access to valuable sanitized data, shared specifically to facilitate robust valuation models.
- **Company disclosures:** Publicly traded companies may disclose significant deals that have a notable impact on their profit or loss statements. Additionally, biotechnology and pharmaceutical companies often publish press releases to highlight major completed transactions.
- **Disclosures to regulatory bodies:** Disclosures made to regulatory bodies, such as the US Securities and Exchange Commission, can serve as a valuable source of information regarding deals of significance.
- **Subscription and proprietary databases:** Several data providers offer subscription-based access to licensing and acquisition information, which can be a valuable resource for gathering relevant data.
- **Court judgments:** In many countries, the resolutions of IP infringement cases are published and can provide insights into comparable deals.
- **Industry associations:** Associations focused on innovation and technology transfer, such as the Association of University Technology Managers,[1] often manage data repositories containing information on deals completed by their members. This information is typically available to members for free and accessible to others for a fee. (For example, the Licensing Executives' Society International[2] periodically publishes a survey of user data on biotechnology and pharmaceutical royalty rates.)

By exploring and leveraging these diverse sources, IP valuators can collect comprehensive data to inform their market approach valuation. These sources offer a wide range of deal-related information, facilitating a more accurate assessment of the value of early-stage drug candidates within the biotechnology industry.

Extracting useful data toward economic truth

To extract the most useful data from the gathered information, innovation professionals must adopt a critical approach. They should focus on key deal terms and financial considerations that directly impact valuation. Such data may include upfront payments, milestone payments, royalties, equity stakes, deal structures and contingent considerations. (Over the past 10 to 15 years option rights in license agreements and contingent value rights in firm acquisitions have become relatively common in life science deals.) It is important to consider the specifics of each deal, such as the stage of development, therapeutic potential, market size, competitive landscape and the involvement of reputable industry players. By carefully evaluating this information, professionals can uncover patterns and trends that bring them closer to economic truth.

Let us look at Case study 1 to consider how BioTech may use the market approach to value the cystic fibrosis (CF) project.

Case study 1. Using the market approach to value a phase I drug candidate

The CEO considers that the venture capital providers she seeks investment from may also hold useful comparable data for companies in their investment portfolios. She consults contacts in her network who share sanitized information on recent deals completed by their portfolio companies. In addition, the CEO has one of her analysts trawl through several information sources to identify other recent relevant deals. The analyst compiles all the data into a table to facilitate a comparison for the CF project (Table 2).

1 https://autm.net/surveys-and-tools/databases
2 https://lesi.org/publications/les-royalty-rates-and-deal-terms-surveys

Table 2. Comparable license deals to support valuation of the cystic fibrosis project

Factors	Deal 1	Deal 2	Deal 3	Deal 4	Deal 5
Transaction type	Licensing agreement	Partnership	Acquisition	Investment and co-development	Licensing and collaboration agreement
Transaction details	License of IP with know-how	Collaboration agreement: Joint research and development efforts with cost and profit-sharing arrangement		Joint development of a specific drug candidate with cost and profit-sharing arrangement	In addition to license, research collaboration: Biotechnology company E and University U collaborate on preclinical and clinical development with shared expenses
Parties involved	Biotechnology company A and pharmaceutical company X	Biotechnology company B and biotechnology company Y	Pharmaceutical company Z and biotechnology company C	Venture capital firm V and biotechnology company D	Biotechnology company E and University U
Therapeutic area	Oncology	Neurodegenerative diseases	Rare genetic disorders	Immunology	Infectious diseases
Stage of development	Phase II	Phase I and II	Phase III	Phase I	Phase II and III
Financial terms	Upfront payment: USD 30 million. Royality rate: 10 percent on net sales. Milestone payments: Up to USD 50 million based on regulatory and commercial achievements	Equity investment: Biotechnology company Y invests USD 15 million for a 20 percent stake in biotechnology company B	Acquisition price: USD 100 million in cash and stock. Contingent payment: an additional USD 50 million based on achieving specific clinical development milestones	Series A funding: Venture capital firm V invests USD 20 million in biotechnology company D in exchange for preferred shares	Licensing fee: Biotechnology company E pays USD 5 million upfront to University U for exclusive rights to a novel technology

Source: Author

With these data, BioTech can determine how the CF project compares to recent deals and determine reasonable terms for its negotiations with Pharmacorp. The deal structure they produce should be similar to the trade deals they are comparing against. The following steps may be helpful.

Step 1: Assess the specific attributes of BioTech's drug candidate – BioTech's drug candidate is a phase I CF project. It is a proposed cure for CF, which would be the first of its kind. The market potential for the CF treatment is estimated to be around USD 6 billion per year globally. The rNPV estimated earlier in the income approach chapter is USD 70.45 million.

Step 2: Compare attributes with comparable deals – Based on the comparable deals provided, deal 1 (licensing agreement in oncology) and deal 3 (acquisition in rare genetic disorders) are relevant in terms of therapeutic area and development stage. These deals can provide insights into the potential valuation of BioTech's CF assets.

Step 3: Adjust values based on differences seen in comparable deals (deal 1 and deal 3) – In this step, we need to consider the specific attributes of BioTech's CF project asset and adjust the values of the comparable deals. Here are some potential adjustments to consider:

– **Uniqueness:** Since BioTech's CF asset is a proposed cure and the first of its kind, it may be considered more valuable than other comparable deals in terms of its potential market

impact and competitive advantage. Therefore, we can apply a scaling factor to increase the valuation estimates derived from the comparable deals.
- **Development stage:** As BioTech's CF asset is in phase I, it is relatively early in the development process compared to comparable deals. This introduces additional risk and uncertainty. We can apply a risk adjustment to reduce the valuation estimates of the comparable deals to account for the higher risk associated with BioTech's assets.

To adjust the values of the comparable deals, we may apply scaling factors or adjust based on these factors. A scaling factor, in the context of valuation, is a multiplier used to adjust or normalize the values of comparable transactions or assets. It is applied to aligning the characteristics of different deals or assets, making them more comparable and suitable for analysis.

Step 5: Perform rNPV analysis for each comparable deal – This can be carried out by considering the expected cash flows, discount rate and risk factors associated with each therapeutic area and development stage. The process is described in the income approach.

Step 6: Incorporate the rNPV of the CF asset – Incorporate the rNPV of the CF asset obtained through the discounted cash flow model, which is estimated at USD 70.45 million, into the valuation analysis. This reflects the expected value of the CF asset based on its projected cash flows and risk considerations.

Step 7: Conduct sensitivity analysis – To ensure robustness of the valuation, it is crucial to conduct sensitivity analysis by varying key variables such as peak sales estimates, discount rates, development timelines and regulatory risks. This analysis will help assess the impact of different scenarios on the valuation estimate and identify the key drivers of value. Below, we expand briefly on the parameters you might consider varying to conduct a sound sensitivity analysis.

Growth rate: Vary the projected sales growth rate of the CF asset. Increase or decrease the growth rate to assess its impact on the valuation. Higher growth rates may lead to higher valuations, while lower growth rates may result in lower valuations.

Growth rate: Vary the projected sales growth rate of the CF asset. Increase or decrease the growth rate to assess its impact on the valuation. Higher growth rates may lead to higher valuations, while lower growth rates may result in lower valuations.

Discount rate: Vary the discount rate used to calculate the present value of future cash flows. Increase or decrease the discount rate to understand its effect on the valuation. A higher discount rate would reduce the present value and result in a lower valuation, while a lower discount rate would increase the present value and lead to a higher valuation.

Success probabilities: Adjust the probabilities assigned to the occurrence of milestones in the rNPV analysis. Increase or decrease the success probabilities to evaluate their influence on the valuation. Higher success probabilities would increase the expected cash flows and lead to a higher valuation, while lower success probabilities would have the opposite effect.

Scaling factor: Modify the scaling factor applied to adjust for the uniqueness of BioTech's CF asset. Increase or decrease the scaling factor to assess its impact on the valuation. A higher scaling factor would amplify the valuation, reflecting the higher value placed on the unique nature of the asset.

Considerations when using the market approach

The market approach, specifically the comparables method, offers valuable insights when valuing early-stage biotechnology IP assets. This approach is especially valuable if values for truly comparable transactions can be obtained, despite the challenges that are involved. This approach is favored by investors due to its reflection of real-world transaction values. It is relatively straightforward to calculate and can be justified by comparing the IP under review

with several recent deals. However, there are several considerations and challenges associated with using the comparables approach in this context:

The uniqueness of IP poses a challenge

IP assets are inherently distinct, making it difficult to find direct comparables that closely match the IP under evaluation. The scarcity of similar transactions limits the availability of precise benchmarks for valuation purposes. For instnce, pharmaceutical technical data is not disclosed in deal summaries or press releases, and superficially similar compound assets may have different developability characteristics; in addition, some deals may include back-up compounds that are not mentioned in public statements and other deals may not.

Maturity is another critical factor to consider

Trade deals can occur at various stages of development, ranging from the discovery phase to preclinical and clinical trial phases. The value of an IP asset can significantly vary depending on its stage of development. A deal completed during the preclinical stage is likely to be valued lower than one concluded at the end of phase II trials. The disparity in risk burden and time to market between these different stages affects the valuation outcomes.

The negotiating parties involved in trade deals also influence the valuation process

Stakeholders can include universities, investors, biotechnology companies, and pharmaceutical companies. Universities often contribute at the upstream end of the development process, focusing on discovery and preclinical stages. In contrast, biotechnology and pharmaceutical companies have a more extensive downstream reach, including clinical trials and market access. Consequently, deals between universities and biotechnology companies may tend to be smaller compared to those between biotechnology and pharmaceutical companies.

Consideration of the macroeconomic environment is vital when examining comparable deals

It is crucial to limit the analysis to a common macroeconomic context. Deals conducted during challenging economic conditions such as recessions, pandemics or wars may not be directly comparable to those conducted during periods of economic growth and stability. Economic factors can significantly influence the terms and values of transactions, and comparisons across different economic environments may lead to inaccurate valuations. Also, the type of buyer may also have an effect: sometimes a firm may have an undisclosed reason for acquiring, e.g., an impending firm sale or restructuring, and this may affect the price that it is willing to pay.

In summary, while the market approach and comparables method have their merits in valuing early-stage biotechnology IP assets, various factors must be considered. The uniqueness of the IP, the stage of development, the negotiating parties involved and the macroeconomic environment all play a significant role in determining the appropriate comparables and ensuring accurate valuation outcomes.

In general, it is advisable to use more than one valuation technique; the combined use of rNPV and the market approach (comparables) might be a good default choice in many circumstances and is a common practice.

3 The income approach

This chapter looks at the income approach. This method calculates value based on projected future cash flows, adjusted for the high risks inherent in biotech development. The guide emphasizes the widespread use of risk adjusted Net Present Value (rNPV), which applies success probabilities at each clinical and regulatory milestone to model potential outcomes credibly. The chapter stresses that as assets advance through the pipeline and more reliable data emerge, the income approach becomes a cornerstone of biotech valuation.

Discounted cash flows and net present value

Discounted cash flow is a commonly used valuation method that estimates the value of IP by determining the expected future cash flows resulting from the development and commercialization of said IP. In this chapter, we will introduce cash flow statements and how they are used to monitor the financial health of an asset, which in this case is IP. In addition, we will discuss the concept of discounting, which allows us to determine the net present value (NPV) of future cash flows.

With this conventional valuation approach, the valuer determines the nature of cash flows for the project under development. Cash flow is the movement of money in and out of the company, typically to develop, produce, and sell goods and services. The cash flow statement summarizes a company's cash inflows and outflows over a specified period. Cash flow statements and other financial reports allow companies, investors and analysts to determine the financial health of a company. An example of a cash flow statement is shown in Table 3.

Table 3. Example of a cash flow showing money in and out of a small business (Company ABC)

	Month 1	Month 2	Month 3	Total
Cash on hand (beginning of month)	**$20,000.00**	**$29,100.00**	**$45,950.00**	
Cash receipts				
Cash sales	$25,000.00	$30,000.00	$36,000.00	$91,000.00
Returns and allowances			$200.00	$200.00
Other receipts				
Total cash receipts	$25,000.00	$30,000.00	$35,800.00	$91,200.00
Total cash available	$45,000.00	$59,100.00	$81,750.00	
Cash paid out				
Advertising	**($3,000.00)**			**($3,000.00)**
Commissions and fees	($250.00)	($300.00)	($360.00)	($910.00)
Contract labor		($200.00)		($200.00)
Materials and supplies (in COGS)	($1,200.00)	($1,200.00)	($7,500.00)	($9,900.00)
Mortgage	($2,500.00)	($2,500.00)	($2,500.00)	($7,500.00)
Office expense	($1,000.00)	($1,000.00)	($1,000.00)	($3,000.00)
Repairs and maintenance	($100.00)	($100.00)	($100.00)	($300.00)
Utilities	($150.00)	($150.00)	($150.00)	($450.00)
Salaries	($5,000.00)	($5,000.00)	($5,000.00)	($15,000.00)
Subtotal	($13,200.00)	($10,450.00)	($16,610.00)	($40,260.00)
Loan principal payment	**($1,500.00)**	**($1,500.00)**	**($1,500.00)**	**($4,500.00)**
Capital purchases	($1,200.00)	($1,200.00)	($1,200.00)	($3,600.00)
Other startup costs				
Total Cash Paid Out	**($15,900.00)**	**($13,150.00)**	**($19,310.00)**	**($48,360.00)**
Cash on hand (end of month)	**$29,100.00**	**$45,950.00**	**$62,440.00**	**$62,440.00**

In Table 3, the small business starts with USD 20,000 in hand and in the first month makes USD 25,000 in sales. The business has several expenses including advertising, labor, and utilities. In addition, there is an outstanding loan that is steadily repaid each month. The company also pays monthly for some capital purchases.

In this example, the business has a net positive cash flow at the end of each month. The cash flow statement allows the small business to monitor its financial health. Similarly, when considering IP commercialization, we must consider the costs of development, any investments raised to support exploitation and, eventually, inflows of cash due to sales. It is important to note that loan repayments and capital purchases, while contributing to overall cash outflows from the business, are segregated to provide clarity and transparency. In the case of the

loan for example, this separation allows users of the financial statements to analyze the impact of borrowing and repayment activities on the company's cash flows separately from other activities.

For IP valuation, we assume that the IP under review is at an early stage and therefore either at discovery, pre-clinical or phase II trials. The cash flow developed addresses the remaining development process as the IP undergoes clinical trials and regulatory review, to market entry. Post-market cash flows span the IP's useful remaining lifetime, which is typically the period up to patent expiry or peak sales.

The process may take the following steps:

Step 1: Determine pre-commercialization cash flows

We need to consider the costs of acquiring IP, in case it has not been developed in-house, as well as pre-clinical and clinical studies, operations, and administrative costs. To appropriately estimate these costs, it may be necessary to simulate different scenarios to account for higher-than-expected costs, delays in conducting studies and fluctuations in operational and administrative costs. Cash flows are typically negative (Clinical Research, 2019) in the pre-market phase of the project, as shown in Table 4.

Table 4. Example of pre-commercialization cash flow for drug candidate under development

Stage of development	%	Phase I (USD millions)		Phase II (USD millions)		Phase III (USD millions)			Approval
Project year		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Total benefits (USD million)		**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Development costs (USD million)									**3**
Site monitoring	15	0	0	1	1	1	1	1	
Staff, physicians and clinical associates	34	1	1	1	2	2	2	3	
Patient recruiting	3	0	0	0	0	0	0	0	
Site recruiting and retention	16	0	0	1	1	1	1	1	
Lab costs	8	0	0	0	0	0	1	1	
Source data verification	4	0	0	0	0	0	0	0	
Clinical procedures	20	0	0	1	1	1	1	2	
Launch costs									50
Total development costs (USD million)		**2**	**2**	**3**	**5**	**5**	**7**	**8**	**53**
Net cash flow (USD million)		**–2**	**–2**	**–3**	**–5**	**–5**	**–7**	**–8**	**–53**
Cumulative (USD million)		**–2**	**–4**	**–7**	**–12**	**–17**	**–24**	**–32**	**–85**

Source: Author

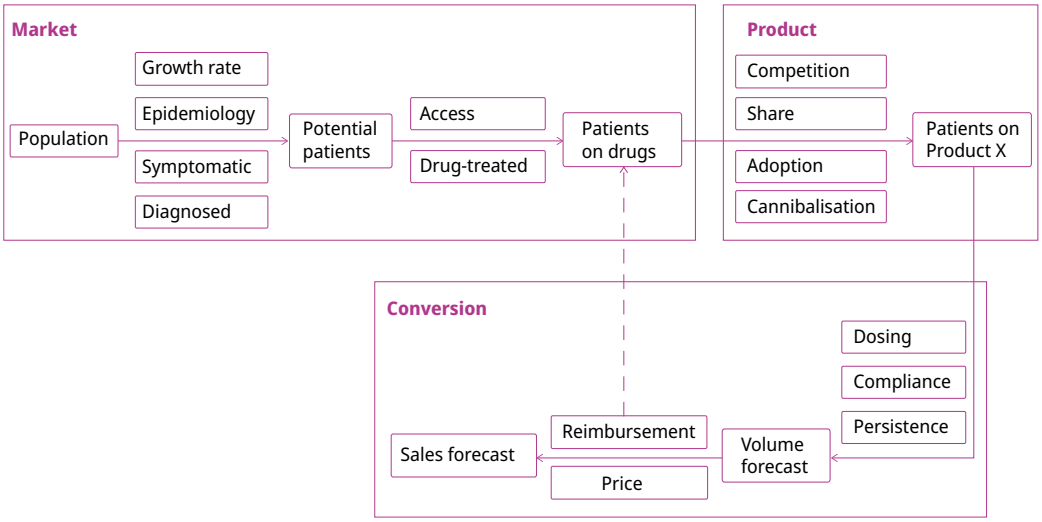
Step 2: Determine post-commercialization cash flows

After market entry, cash flows inflect positive due to revenues from product sales. Here, we must consider product sale evolution where product sales grow from a low base, peak over time and eventually depreciate as market capitalization is lost due to product obsolescence, competition, and other factors. Estimation of sales can be challenging due to the wide range of value drivers in the marketplace. These include the size of the target patient population, our drug pricing, uptake rates in various target markets, dosing requirements, competition (including from non-medical solutions), growth forecasts, obsolescence, competing drugs entering the market or as our product approaches the end of its useful life.

Figure 2 shows an overview of the forecasting approach typically used in the biotechnology and pharmaceutical sectors (Cook, 2016). Typically, we start with estimating the number of people who suffer from the condition that our therapeutic agent can treat. We then determine from this figure how many are likely to take remedial therapies. We assume that this subset

of the population has been diagnosed and may be symptomatic. From this group, we further estimate the number that may have access to relevant drugs that have been approved in the region we are scrutinizing. At this point, we can consider the existing market for the drug under scrutiny and its competitive landscape. We can then consider how this figure (patients on drug X) converts into sales for the drug developer. Drug pricing is complex and subject to negotiations between pharmaceutical companies and national health services as well as the highly fragmented private health care sector comprising insurers, pharmacy benefit administrators, and other stakeholders. The situation is further complicated by the trend toward value-based pricing for prescription drugs.

Figure 2. Generalized components of a new product forecast algorithm



Source: Cook (2016)

Step 3: Discounting each cash flow

The cash flows estimated in steps 1 and 2 not only occur at different points in time, but they also carry an element of unpredictability in terms of size and the likelihood of occurring. Once we estimate these future cash flows, we discount and sum them to determine the NPV of the IP. Discounting refers to the process of determining the present value of an opportunity, which is realized at a future date. The discount rate applied is a single value, which combines several factors including:

- **Time value of money –** The concept that money today is worth more than money tomorrow.
- **Cost of capital –** The rate of return a company must earn before generating value.
- **Probability of success –** Estimating uncertainty or risk of the cash flows.

We will first explore the concept of time and value of money. For example, a dollar today is worth more than a dollar will be worth in one year. We must apply an interest rate to address the depreciation of the dollar, to preserve its present value. This is like applying an interest rate to a dollar in a savings account. Typically, interest rates compound over time, such that if we applied a 10 percent interest rate on the dollar, it would be worth USD 1.10 after the first year and USD 1.21 after the second year. For the purposes of valuation, the interest rate applied comes from national treasury bonds with long maturities in the country (e.g., the United States of America) or region (e.g., the European Union) of interest for the valuation activity.

To discount each cash flow the formula shown in Equation 1 is typically used.

Equation 1. Formula used to discount cash flows

$$DCF = \frac{C_{t0}}{(1+r)^{t0}} + \frac{C_{t1}}{(1+r)^{t1}} + \cdots \frac{C_{tn}}{(1+r)^{n}}$$

DCF = Discounted cash flow
C_{ti} = cash flow in period i
t = time period
r = discount rate (%)
n = number of time periods (years)

The cost of capital is partly dependent on the company's profile from an investor's perspective. For example, a well-established biotechnology company with a history of successfully taking drugs to market may be considered lower risk than a startup established to develop and market one drug candidate. In the latter case, the company is likely to be considered high risk, and as a result may be subject to higher-than-average costs of capital. A positive NPV or discounted cash flow indicates that the project exceeds the firm's discount rate and would be valuable to pursue. A negative NPV indicates that the project will not make a sufficient return to cover the discount rate and should be abandoned.

Some valuation professionals argue that using a single value to accommodate several variables masks the complexity of the drug development process and therefore outputs a less accurate valuation than when a risk-adjusted approach is used (Avance, 2021a).

Cost of capital

Cost of capital is an important factor to consider in IP valuation and it is helpful to understand its components and their relationships. The rate on long-term government bonds is often perceived as a *risk-free rate* by financial market participants. This rate serves as a baseline for riskier financing activities conducted by companies. Large companies typically raise funds by issuing shares and taking on debt through corporate bonds, both of which incur costs.

In an equity issue, an investment bank facilitates the issuance process and existing shareholders may have the option to purchase new shares. On the other hand, when issuing corporate bonds, the company must pay interest based on the current risk-free rate and the projected rate over the bond's lifespan (which can extend up to 10 years). Additionally, a risk premium is included to account for the market's assessment of the firm's activities. The cost of capital for a company is the culmination of these charges, blended based on the company's equity (share) and bond (debt) composition.

For many large pharmaceutical firms, the cost of capital has ranged from 7 to 9 percent over the past 15 years. Analysis reports produced by prominent investment banks often provide the cost of capital rate for specific firms, serving as valuable references. However, small biotechnology firms may face substantially higher costs of capital. Raising new equity can be challenging and expensive for them and traditional debt financing may not be a viable option.

Understanding the cost of capital is essential in determining the appropriate discount rate for cash flows in IP valuation. It reflects the return expected by investors for the level of risk associated with the investment. By considering the specific circumstances of the firm and its industry, including the size, stage of development and market conditions, a realistic and customized cost of capital can be determined, enabling a more accurate valuation of the IP assets.

Project risk

Project risk is a crucial aspect to consider in IP valuation and it is closely related to the concept of the risk-free rate and the cost of capital. The risk-free rate represents the time value of money for a project that carries no risk, while the cost of capital reflects the time value of money for a project with the same level of risk as the average project within a firm. In practice, many large firms establish a corporate rate at the beginning of the year, which serves as a benchmark for most valuations, enabling clear comparisons among competing projects.

However, for projects perceived as high risk, a higher discount rate may be applied to account for the elevated level of risk.

Determining the appropriate discount rate to reflect project risk is a challenging task. It requires a careful assessment of the specific risks and potential outcomes associated with the project. The use of a higher discount rate for riskier projects aims to capture the additional compensation required by investors for taking on greater uncertainty. However, one major drawback of solely adjusting the discount rate to account for project risk is that the effects of risk are not explicitly visible in the valuation output. Users of the valuation information may not easily discern the separate impacts of the cost of capital and risk on project value.

To address this issue, a more effective approach is to adjust the cash flows (the numerator in the valuation equation) to incorporate project risk separately from the cost of capital (the denominator). By doing so, observers can clearly see and evaluate the influence of each factor, promoting a more comprehensive understanding of the expected cash flows and risk implications. Determining the expected cash flows requires careful consideration and judgment by the project team. However, relying solely on one scenario may limit the assessment to a single set of outcomes. Therefore, the rNPV approach is highly valuable, as it explicitly considers a range of future scenarios, providing a more comprehensive evaluation of project value.

Considering project risk and using the rNPV approach allows decision-makers to assess the potential impact of different outcomes and make informed decisions based on a more comprehensive understanding of the project's value. It encourages a thorough examination of the expected cash flows under various scenarios, ultimately leading to a more robust and realistic valuation. The rNPV is described in detail in the following section.

Risk-adjusted net present value

The rNPV, also known as the probability-weighted expected return method or expected NPV method, is a refinement of the discounted cash flow approach, where future cash flows are adjusted based on their probability of success. Here, we separate the cost of capital from the probability of success of the project development. The rNPV is the most popular, and therefore de facto valuation method for biotechnology assets and firms, and can be calculated using the formula in Equation 2.

Equation 2. Formula for calculating the risk-adjusted net present value

$$rNPV = \sum_{t=0}^{n} \frac{R_0 C_t}{(1+r)^t}$$

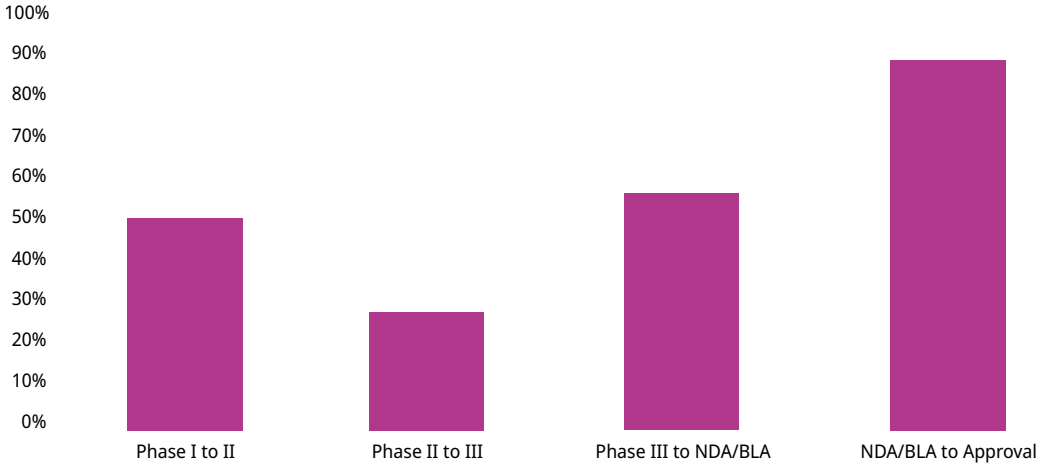
rNPV = risk adjusted net present value
n = number of time periods (years)
t = 0 present day (now)
R_0 = probability of cash flow now
C = cash flow period
r = discount rate (%)

The process may take the following steps:

Step 1: Determine the probability of success

Due to the well-established structure of drug development, attrition rates (or inversely, probabilities of success) during clinical trials and at regulatory approval are well documented across different indications, as shown in Figure 3 (Biotechnology Innovation Organization, 2021).

Figure 3. Phase transition success rates for all diseases and modalities



Note: NDA, New drug application; BLA, Biologicals license application.

Note that the data shown in Figure 3 shows attrition rates across several indications. When developing valuation models for a particular indication you should source more precise data relevant only to the indication of interest.

Step 2: Determine influential factors

Other factors play a part in the valuation of biotechnology IP, including partnerships and how useful the product remains during the lifetime of the IP.

Partnerships

Often drug development is conducted through research and development collaborations, which may require the use of background IP or know-how developed by consortia members. The arising, or foreground, IP (candidate molecules) may therefore be co-owned by the collaborators. In addition, partners may share the risk by funding both clinical trials and later marketing activity.

Remaining useful lifetime of IP

Due to the long development timeline in the biotechnology sector, the IP protection strategy must be robust. Applying for patent protection early in the process (e.g., at discovery) may be unwise since it may be more than 10 years before the product enters the market, at which time the remaining useful time is severely diminished. It may be beneficial to delay the patent application to allow the IP owner(s) the opportunity to appropriate as much future value of the product as possible; however, two key risks need to be assessed: the possibility of inadvertent disclosure (which is in the control of an organization, to a significant degree) and the potential for a similar patent application being filed by a competitor (which is outside of the organization's control).

Typically, well-established biotechnology and pharmaceutical companies rely on methods such as trade secrets, and robust non-disclosure clauses in their employment contracts to mitigate disclosure risks, but the second risk cannot be mitigated and is always an issue. Consequently, many large firms will file at a specific point in the 14- or 15-year development cycle (e.g., shortly ahead of the *candidate selection* – the identification of a lead molecule – at approximately 8 to 10 years from potential market launch).

Most research-intensive universities, which are a rich source of early-stage IP (discovery and pre-clinical stage), do not have the resources to develop IP beyond the pre-clinical stage. They are also obligated to pursue academic capital by publishing research outputs, some of which may reveal commercially sensitive insights. These factors make it more challenging for universities to appropriate a significant portion of the future value of IP, compared to

biotechnology and pharmaceutical companies with the resources to operate downstream (clinical trials and market entry).

Considerations when using rNPV

There are several points to consider when using rNPV:

- Assumptions used in cash flow development must be data-driven. One must rely on verifiable information on attrition rates for the indication, project type, and stage of development. The use of external references enables the valuation to be defended internally, within the organization, and potentially, to an external party in a deal negotiation. Some core assumptions and ranges of valuation outputs may be shared in negotiation discussions to support a position on deal terms.
- The rNPV approach is widely accepted by valuation professionals in biotechnology and pharmaceuticals (Avance, 2021b) and should constitute a core method for all practitioners.
- For early-stage IP, the use of comparables is helpful, particularly when preparing to raise finance. Source comparables from recently completed merger and acquisition deals or the financial records of similar public companies.
- When considering collaboration partners or in-licensing IP, focus on how the rNPV is shared between parties. This element is a key part of negotiation discussions in these situations.

Some firms structure expected NPV and rNPV calculations using a decision tree approach. This provides a graphical method for detailing the problem and illustrating the results in relation to the valuing of a phase I drug candidate, as is explored in Case study 2.

Case study 2. Valuing a phase I drug candidate

Pharmacorp, a large pharmaceutical company, has recently failed to secure regulatory approval for a cancer drug and, consequently, shareholder confidence is low. To strengthen its pipeline and reassure shareholders, the company is looking for in-licensing opportunities from universities and biotechnology companies.

BioTech is a mid-sized biotechnology firm with two major projects in its pipeline. One is a phase I cystic fibrosis project while the other is a flagship platform for cancer treatment (TumaBlok). BioTech needs to secure funding to support operations for the next 24 to 30 months.

Pharmacorp encountered BioTech at an industry conference and held some initial discussions about BioTech's pipeline. Pharmacorp thinks that the CF project may be an attractive licensing opportunity.

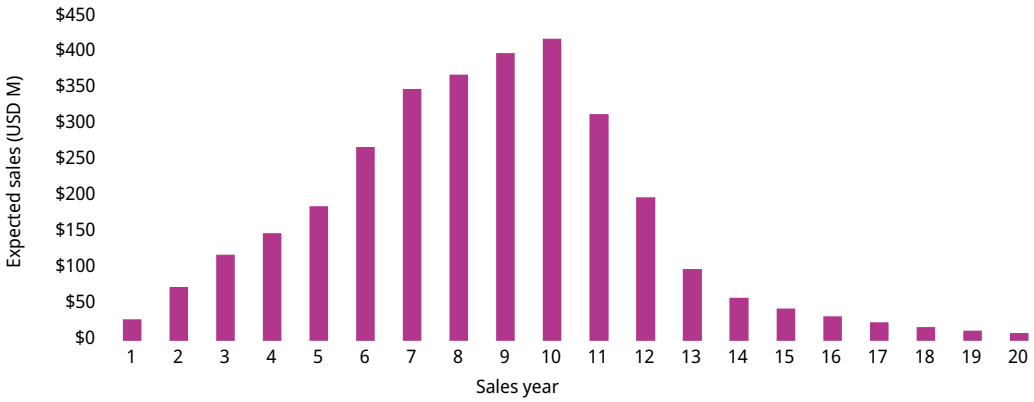
Due diligence The candidate CF treatment seems promising from an efficacy perspective. It is a proposed cure for CF, which would be the first of its kind since patients typically undergo lifelong treatment and care. The market is large, at approximately USD 6 billion a year globally. BioTech is keen to out-license the CF drug to allow the company to focus its efforts on the cancer treatment. Pharmacorp's analysts and finance specialists have estimated the following forward-looking costs for the development of the CF project (Table 5) and the expected sales curve (Figure 4).

Table 5. Associated costs of developing the cystic fibrosis project

Stage of development	Phase I	Phase II	Phase III	Approval	Sales
Cost (USD million)	4	8	24	2	
Duration (years)	2	2	3	1	
Probability of success (P) (%)	60	40	80	90	
Costs of goods sold (%)					25
Launch costs (USD million)					50
Peak sales (USD million)					420

Source: Author

Figure 4. Expected sales projections for the cystic fibrosis project



Based on the data in Figures 4 and 5, and utilizing a discount rate (*r*) of 10 percent, Pharmacorp's analysts have built a risk-adjusted discounted cash flow model to assess the value of IP as a basis for deal negotiation (Table 6).

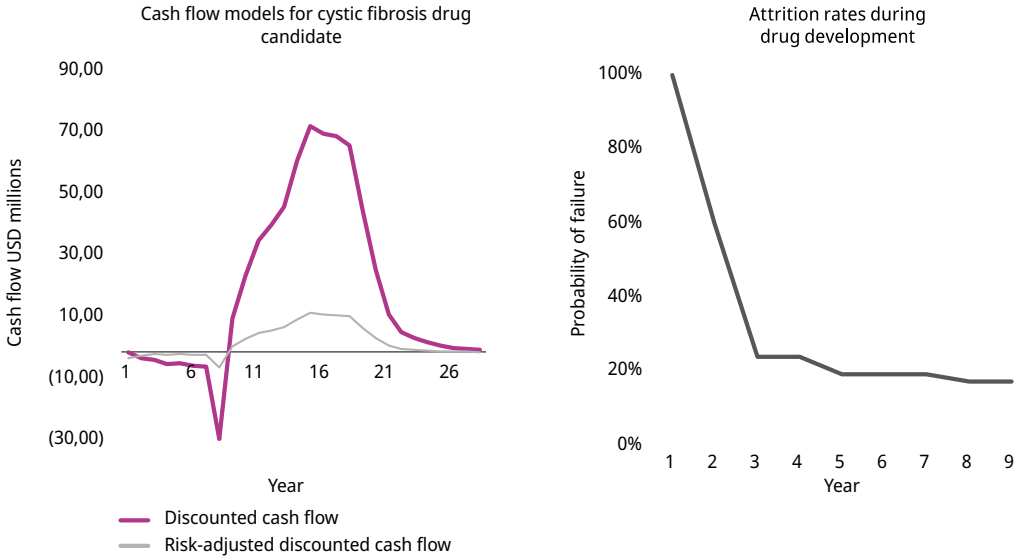
Table 6. Cash flow forecast for the cystic fibrosis opportunity, to peak sales

Stage of development	Phase I	Phase II	Phase III	Approval	Sales
Cost (USD million)	4	8	24	2	
Duration (years)	2	2	3	1	
Probability of success (P) (%)	60	40	80	90	
Costs of goods sold (%)					25
Launch costs (USD million)					50
Peak sales (USD million)					420

Source: Author

Pharmacorp's analysts have valued the CF opportunity as if it were an internal project, resulting in the data shown below.

Figure 5. Cash flow forecasts (discounted and risk-adjusted) for the cystic fibrosis project, overlaid with the cumulative probability of success



Based on this model, Pharmacorp's analysts can determine two key indicators of deal performance: the expected NPV of the deal and the internal rate of return (IRR). These indicators are used to compare this opportunity against others available to Pharmacorp. Due to the sharp decline in sales predicted (Figure 5), the rNPV of the project is calculated only up to peak sales (project year 18), by summing the yearly risk-adjusted discounted cash flows for each year up to year 18. This yields an rNPV of USD 70.45 million. It is worth reiterating the approach used to determine the rNPV. One may take the following steps:

- **Estimate the expected cash flows:** Start by estimating the expected cash flows associated with the drug candidate's development and commercialization. Consider factors such as research and development costs, regulatory expenses, manufacturing and production expenses, marketing and sales costs, and projected revenues, for different potential outcomes, over the drug's lifecycle.
- **Assign probabilities to different scenarios:** Assess the probabilities of various scenarios that may impact the drug's success and commercialization. This could include factors such as clinical trial results, regulatory approval, market acceptance, competition and patent expiration. Assign probabilities to each scenario based on expert judgment, historical data or industry benchmarks.
- **Calculate the risk-adjusted cash flows:** Multiply each expected cash flow by its corresponding probability. This step accounts for the likelihood of each scenario occurring and adjusts the cash flows accordingly. Higher-risk scenarios may be assigned lower probabilities, leading to lower weighted cash flows.
- **Discount the risk-adjusted cash flows:** Apply a discount rate to the risk-adjusted cash flows using the organization's standard discount rate (which reflects its cost of capital). The discount rate should not reflect the drug's specific risk profile, including factors such as the stage of development, market potential and regulatory uncertainties, as these factors have been incorporated into the set of cash flows and probabilities. Discounting the cash flows reflects the time value of money to the specific organization that is evaluating the project and provides the present value of the expected future cash flows.
- **Sum up the risk-adjusted present values:** Sum up the discounted cash flows to determine the rNPV. A positive rNPV indicates that the drug candidate's expected cash flows, after considering the associated risks, outweigh the costs and meet the required return on investment. A negative NPV suggests that the drug candidate may not generate sufficient returns to justify the investment.

One feature of this approach is that a large pharmaceutical firm and a biotechnology company may have different valuations of the same project since, in most cases, the cost of capital to

the two firms is different. From one perspective, this may seem illogical – surely a project has a specific value? However, the NPV and rNPV methods do not determine a *true* or *market average* value of a project, it uses a specific discount rate that is linked to a particular firm and so it assesses the value of the project to the firm that is undertaking it. Positively, in the usual business context of internal evaluation and review, this is the information that is required by the commercial team and by senior management. In large firms, tax effects are often considered in NPV or rNPV valuations as a final stage in the analysis.

By applying the rNPV approach, decision-makers can better evaluate the value of an early-stage drug candidate, considering the inherent uncertainties and risks in drug development. This analysis helps assess the potential profitability, make informed choices regarding resource allocation, licensing agreements, partnerships or further development decisions, and compare different investment opportunities based on their risk-adjusted profitability. Incorporating risk adjustments into the NPV calculation provides a more realistic assessment of the investment's value, considering the uncertainties and risks involved, and helps evaluate whether the expected returns adequately compensate for the perceived risk.

From this analysis, we observe that the effect of risk adjustment becomes clear, with cash flows heavily modulated by the probability of success, thereby diminishing the chances of market entry. Notably, we modulate costs by the cumulative probability, as subsequent costs of development will not be incurred if the project fails a developmental milestone.

Next, we calculate the IRR for the project, by iterating the discount rate until the rNPV at peak sales equates to zero. By doing this, the analysts are determining the rate of return of the project compared to the discount rate and, provided the IRR is higher than the discount rate, the project is financially attractive. The analyst's model yields an IRR of approximately 35 percent, significantly above Pharmacorp's 10 percent discount rate.

The internal rate of return

IRR is a metric commonly used in financial analysis to estimate the profitability of a potential project or investment and as a way of comparing multiple opportunities. The IRR is the discount rate at which the expected NPV, i.e., the sum of risk-adjusted discounted cash flows, equals zero. If the calculated IRR is above the cost of capital (discount rate) for the company evaluating the project, then in theory the project is profitable. If the IRR is lower than the cost of capital (discount rate), then it would theoretically cost more to fund the project than the expected returns from it, making it unprofitable.

The advantage of using IRR to evaluate investment opportunities or potential projects is that it allows for the comparison of multiple projects through a single value. Although IRR is a popular way of estimating the returns and profitability of a project or investment, it is typically used in conjunction with other factors when evaluating an investment decision.

To understand the concept of IRR, let us consider an example. Suppose you are considering investing in a biotechnology project to develop a new drug. The project requires an initial investment of USD 1 million and is expected to generate cash inflows of USD 300,000 per year for five years. You want to determine the IRR of this investment.

To calculate the IRR, you need to find the discount rate at which the present value of the cash inflows equals the initial investment. You can start by assuming a discount rate, for example, 10 percent. You discount each cash inflow to its present value using the discount rate and then sum up these present values. If the sum is equal to the initial investment, then the assumed discount rate is the IRR. If not, you adjust the discount rate and repeat the calculation until you find the rate that makes the NPV zero.

Let us say you calculate the present value of the cash inflows at a 10 percent discount rate and find that the sum is USD 700,000. Since this is less than the initial investment of USD 1 million, you know that the IRR must be higher than 10 percent. You adjust the discount rate to 15 percent and repeat the calculation. This time, you find that the sum of the present value is USD 1.2 million, which is higher than the initial investment. Therefore, you can conclude that the IRR is between 10 and 15 percent.

In this example, the IRR represents the annualized rate of return that would make the project's NPV equal to zero. If the IRR is higher than the required rate of return or the cost of capital, it indicates that the investment is potentially profitable. On the other hand, if the IRR is lower than the cost of capital, it suggests that the project may not meet the required return threshold and could be considered less attractive.

The relationship between the discount rate and IRR is that the discount rate is used to calculate the present value of cash flows, while the IRR is the rate at which the present value of cash inflows equals the initial investment. The IRR provides a way to compare the potential returns of an investment with the discount rate or the cost of capital to determine its feasibility and profitability.

The IRR approach

The IRR is a useful metric for assessing the rates of return and relative attractiveness of different projects. However, it has certain limitations. The IRR does not provide information on the magnitude of potential cash returns, as it focuses solely on the percentage rate of return. On the other hand, the NPV and rNPV methods evaluate cash returns at a fixed discount rate, offering insights into the size of potential cash returns to the firm. These different characteristics drive the application of these techniques in specific contexts.

The IRR is commonly used in measuring the returns of venture capital and private equity funds. In such cases, potential investors, like pension funds, are interested in knowing the return that could be generated for each million pounds invested, making the rate of return an appropriate metric. On the other hand, NPV is widely employed in large firms as the primary valuation approach, enabling the comparison of potential returns across different projects conducted over time, by evaluating their value in terms of cash today, which is typically the most relevant information.

However, there are drawbacks associated with using the IRR approach. If the cash flows change signs (positive to negative or vice versa) more than once throughout the project's lifespan, the calculation may yield multiple answers, causing confusion in interpretation. Additionally, two projects with different cash flows and profitability in terms of cash returns may have the same IRR, depending on the sequencing of the cash flows.

It is important to consider these limitations and select the appropriate valuation method based on the specific context and objectives of the analysis. While IRR can provide insights into relative rates of return, NPV and rNPV offer a more comprehensive assessment of the potential cash returns and the value of these returns to the firm.

4 The real options method

The real options method captures the value of strategic flexibility, such as whether to continue, delay, or abandon a development program as new data become available. In biotech, where uncertainty is high and staged decisions are common, this method allows valuation to reflect the option like nature of clinical trial investment. The chapter highlights that real options analysis is particularly suited to early and mid stage biotech assets, complementing rNPV to reflect uncertainty more dynamically.

The rNPV method is powerful and defensible to stakeholders such as decision-makers, potential licensees, and IP asset acquirers. As a result, rNPV is a popular and often chosen valuation method for life sciences assets. However, the approach is rigid in the sense that it simulates a single scenario where the project undergoes clinical trials and enters the market. rNPV is designed for project managers to make go or no-go decisions at the outset only without accommodating new information that may change the trajectory of the project. Decision-makers must alter their plans to account for real-world market conditions. For example, clinical trial results may revea further uses that are attractive enough to call for additional studies; a new competitor may enter the market and force our drug developer to adjust their sales expectations; new regulations may impact the approval process, resulting in a longer and costlier process than originally expected. There are several ways in which a project's trajectory can change and decision-makers must have the flexibility to adapt to dynamic market conditions when valuing projects.

The need for a more flexible approach in valuing biotechnology and pharmaceutical assets brings us to the real options method. Originally developed in the field of finance it has gained some attention in the valuation of early-stage biotechnology and pharmaceutical drug candidates. This approach is more interactive than other methods and recognizes the inherent complexity and decision-making opportunities in the development process of these assets, allowing for a more flexible approach to assessing their value.

Traditionally, the real options method was used to value financial options, such as *call* or *put* options, where the value of the asset is derived from the underlying security. Over time, researchers and practitioners realized that the same principles could be adapted and applied to valuing real assets, including early-stage biotechnology and pharmaceutical drug candidates. In the context of early-stage drug development, the real options method acknowledges the uncertainties and risks involved, as well as the ability to adapt and modify the development strategy based on new information and market conditions. It recognizes that decisions made throughout the development process can significantly impact the project's value.

The evolution of the real options method toward the valuation of early-stage biotechnology IP has been driven by the unique characteristics of the biotechnology and pharmaceutical industry. Unlike traditional investment projects, drug development involves long timelines, high costs, regulatory challenges and significant uncertainties related to clinical trials, market acceptance and IP protection. By applying the real options method, researchers and investors can capture the value of managerial flexibility and the potential upside associated with positive

outcomes. It enables the estimation of the value of options embedded within the development process, such as the option to continue, expand, delay or abandon a project at various stages.

Decision-makers must determine what options to take to alter the project's trajectory to avoid losses and maximize profits for the company. These options are considered if, for example, a critical factor in the project either deteriorates or exceeds expectations. Options may include:

- **Defer:** Waiting for market conditions to be more favorable before releasing resources. During the height of the COVID-19 pandemic some venture capital providers opted to hold on to cash reserves until market conditions improved, rather than seek out new investment opportunities.
- **Expand or contract:** Changing the scale of the project based on market conditions. For example, a company may build a factory in a way that allows for a partial shutdown if demand for products falls, or alternatively, use a modular design that allows for quick expansion of capacity.
- **Abandon, license or sell:** If a project fails to meet a development or sales milestone, the management can abandon the project to avoid further losses. If the underlying IP has other, out of domain or out of core business applications, the IP owner can license-out or sell, in this manner enabling the recouping some of the costs sunk.
- **Staged investment:** Projects must meet development or sales milestones to trigger further tranches of funding. Investors typically use this approach to minimize the risk of losing money in startups that fail to meet development or sales milestones. It is crucial to properly assess the reasons underlying the failure to meet milestones, as they may well depend on developments that are out of the startup's control, and could also represent opportunities to, e.g., create new and valuable IP.
- **Pivot:** During development or sales, the IP developer discovers a new, out-of-domain or more lucrative application for the IP. They decide to explore the option by investing in additional trials. Exercising the option to pivot likely closes the opportunity to switch back to the original plan due to limited resources to pursue more than one opportunity.

An example of the option to pivot

A biotechnology company has recently completed phase II clinical trials for a renal cancer drug that reduces blood flow to tumors. The results are positive, and the decision is made to proceed with phase III trials. Upon further review of the trial results, the team thinks the drug may be effective in reducing blood flow to other types of solid tumors, such as lung and breast cancer. They decide to conduct a second phase II trial, focusing on lung cancer, while in parallel, proceeding with phase III trials for the renal cancer indication.

Other options include proceeding as originally planned, partnering with others, accelerating activity, and many others. It is the duty of management to evaluate a project and recognize all viable options and determine which to take based on their merit. The propensity to view biotechnology projects as purely binary in their nature, that is, trials either succeed or fail, may mask a range of other options that could be explored.

Options-based pricing

Options-based thinking is crucial in the development of many technologies and products, as there are often embedded options that can significantly impact project outcomes. These options could include the ability to expand the scope of the project, terminate it if necessary, or accelerate expenditures and development. While not all organizations formally conduct real options evaluations, many have adopted processes to identify and map out the embedded options at the outset of a project.

Case study 3 in this guide highlights the types of options that can arise in a pharmaceutical project, illustrating the complex nature of these options. Mapping out these options in a diagram and determining their key aspects can provide valuable insights for project and portfolio planning. Adopting an options-based thinking approach can help firms effectively manage sets of technology projects by considering the potential impact and value of different options.

Beyond this initial step of identifying key options, conducting a formal real options valuation can provide financial values for projects and enable comparison among competing resources within a large company. It can also provide a potential valuation for financing or deal purposes in a biotechnology firm. As a first step in the valuation process, it is important to determine the set of options embedded in the project. This information will typically need to be presented to the internal team and management of the company or, at the very least, outlined to a counterparty in a deal negotiation.

By incorporating options-based thinking and conducting real options valuations, organizations can gain a deeper understanding of the value and potential outcomes associated with their projects. This approach allows for more informed decision-making, strategic planning, and effective resource allocation.

Valuing early-stage biotechnology and pharmaceutical drug candidates using the real options method provides a more comprehensive representation of their potential value in comparison with the previously described valuation methods. It allows decision-makers to make informed choices regarding investment, licensing agreements, partnerships, and other strategic decisions by considering the value of managerial flexibility and the ability to adapt to changing circumstances throughout the development process. This is the key advantage of a real options valuation over an NPV calculation: the real options method explicitly considers flexibility and different future pathways for the project. A standard NPV calculation deals with a single linear pathway; the rNPV method deals with a variety of future scenarios, using a decision tree framework; and the real options method enables explicit modeling of flexibility and growth options that are inherent in a project. One benefit of the binomial pricing real options method is that it allows for discount rates to be varied at different stages of a project development e.g., as risk decreases due to learning.

Financial options trading and the origin of the real options method

Before discussing the specifics of real options valuation, it is worth highlighting the financial origins of this approach. Options to buy or sell stocks and other financial securities have some similarities with technology development projects, but also some important differences, and these characteristics influence very significantly the choice of calculation approach.

Financial options

Some standard financial options are *call* and *put* options on stocks of a publicly traded company. In this context, a *call option* provides the holder with the right, but not the obligation, to buy a share in the specified company at a pre-set price, known as the exercise price. Electing to use the option and to buy the share is termed *exercising the option*. As an example, if the price of a stock at the time of purchase of the option is USD 50 and the option has an exercise price of USD 60, then the option will be used if the price rises above USD 60. If the price at the exercise is USD 70, and if the original option cost was USD 5, then a profit of USD 15 will have been made.

Similarly, *put options* provide a holder with the right, but not the obligation, to force a counterparty to buy an asset at a specific price; these options can be used to protect against falls in asset prices. As an example, if a stock price falls from USD 50 to USD 10 per share, then a put option that allows the holder of the stock to sell at USD 40 per share will be valuable.

A wide set of options (or *derivatives*) can be bought and sold on a set of different financial assets; the core financial securities are called the underlying assets (or *underlyings*), as these underpin the creation and trading of the options. Options may either be exercisable at any time (*American options*) or only at a certain pre-specified time such as three months from purchase (*European options*).

Many real options are analogous to financial *call* options in that the option will be exercised if the value of the project has risen: growth options such as plant or market expansion fall into

this category. Plant closure and contraction can be regarded as being analogous to *put options*. Many real options are American in nature in that the timing of exercise, if it occurs, is not pre-determined but could happen at any suitable point. Other options, such as the outcome of clinical trials, are more analogous to European options in that the change in the value of the *underlying*, i.e., a given project, will be known at a specific future time.

Black-Scholes and analytical solutions

The well-known Black-Scholes equation represents a pricing approach for financial European call options (Black and Scholes, 1973). The derivation of the formula was instrumental in establishing the use of equations (analytical solutions) as pricing approaches for option products and a wide variety of such approaches are now in use for specific option types. The formulae are noted in Equation 3.

Equation 3. Black-Scholes formulae for a call option

$$C = N(d_1)S - N(d_2)Xe^{(-rtT)}$$

$$d_1 = \frac{ln\frac{S}{X} + \left(r + \frac{\sigma^2}{2}\right)T}{\sigma\sqrt{T}} \quad \text{and} \quad d_2 = d_1 - \sigma\sqrt{T}$$

$$P = N(-d_2)Xe^{-rT} - SN(-d_1)$$

C = value of the call option

S = current price of the underlying asset

$N(.)$ = cumulative standard normal distribution

X = strike price of the option

e = base of the natural logarithm

R = risk-free interest rate

T = time to expiration of the option, expressed in years

σ = volatility of the underlying assert's return

Through a financial approach that is known as *put-call parity*, a call option can be replicated with other financial instruments. The derivation of the Black-Scholes approach assumes that this replication is possible and that arbitrage will occur in financial markets: if the call option is priced incorrectly, market traders will buy or sell the replicating portfolio and the option to make a profit. These assumptions of a replicable portfolio and arbitrage are valid in many financial markets and underpin the use of the risk-free rate in the Black-Scholes (and other similar) equations; however, challenges often arise when seeking to apply Black-Scholes or a similar analytical approach to the pricing of real options in an industrial setting.

Challenges in applying the financial pricing approach to real options valuation

In the case of real options, it is often difficult to establish a portfolio that replicates the option, even at an approximate level. Some situations that allow for approximate replication may exist; for example, a market entry option that is "held" by a pharmaceutical company might be approximated by buying shares in similar competing firms. Similarly, some authors have suggested that exploration and trading options held by major oil firms can be partially replicated on a similar basis through the use of shares in competitor firms. Nonetheless, in the case of many real options, it is hard to identify a tradeable replicating portfolio. In the case of a drug development project, or a technology development program, it is frequently difficult to see how the specific project or program could be replicated to allow for mispricing arbitrage to occur. Given the axioms of the Black-Scholes derivation, this suggests that in many cases the Black-Scholes formula is not a valid or appropriate technique to use. Similar challenges can be made regarding many other analytical formulae.

Perhaps less significantly, but notably, standard analytical options pricing approaches rely on the concept that the risk in the underlying asset is separate to the risk of the option and that there is *risk exogeneity* i.e., the creation of the option does not affect the risk of the *underlying*. In other words, the trading of the stock and its performance can be seen as being wholly separate from the buying or selling of any options that are based on the firm's share price, even though the value of the options is dependent on the company's stock price. As many real options are altered, to some degree, by actions of the firm that "holds" the option (e.g., market entry and other growth options), this assumption is not always valid. Fortunately, other option pricing approaches have been developed and some of these can be applied to value the types of real option that arise in product and technology development.

Volatility

A core concept in all option pricing is *volatility*. In a financial setting, this is defined as the variation in the stock price, e.g., the standard deviation of price within a certain time window, such as 30 or 90 days. With a call option, usually high volatility is a good thing: the greater the up and down variation in the price, the greater the chance that the price will rise above the exercise price. The price may also drop, but in this case, the only loss is the purchase price of the option; on the other hand, if the price rises above the exercise price, the gains may be substantial. As many real options are analogous to call options, it may seem that high volatility is a good thing, but care needs to be taken. The value of volatility that is used needs to be carefully assessed given its importance in the pricing approach. Entries into new markets and other inherently risky projects may have high volatilities, but incorrectly setting the volatility values could lead to poor project selection decisions. For example, if a firm wishes to enter a market with which it is unfamiliar, it should research the volatility of the project by looking for similar endeavors by other firms, rather than applying a large volatility number simply because this type of project is little understood in this particular firm.

Real options valuation methods

There are four main approaches to using the real options method, namely formulae (Black-Scholes and similar analytical solutions); the binomial option pricing model (BOPM) through which decision trees are developed; simulations; and finite differences (Bogdan and Villiger, 2010). In this guide, we will focus our efforts on resolving real options with decision trees, as they are easy to model, resolve, and visualize. With decision trees, the user can model a diverse range of options, including those with added complexity.

Decision-makers in the biotechnology sector prefer valuation models that are perceived as more transparent and easier to comprehend and defend. The BOPM, with its step-by-step tree-based approach, may provide decision-makers with a clearer understanding of the valuation process and the underlying assumptions compared to the Black-Scholes model. The BOPM allows for more flexibility in capturing the complexities of early-stage biotechnology assets, such as changing volatility and multiple decision points. It provides a visual representation of possible future outcomes and can be seen as a more intuitive approach for decision-makers. While the BOPM may require more computational resources and time compared to the Black-Scholes model, decision-makers may be willing to invest in a more comprehensive model if it enhances their understanding and confidence in the valuation results. Based on this assertion, we will focus on applying the BOPM approach in the use case example in the next section.

Modeling and resolving decision trees

One of the simplest examples of decision trees is the binomial recombinant tree, which starts with a determination of value drivers for the project. These include estimations of peak sales and their expected growth rate, duration (e.g., yearly), probability of success during development and in the market, estimated margin, costs during development, launch and operating expenses, and volatility in peak sales estimates. From this point, we model the project's value (V_t) from the present day to a time step (Δt) in the future where the market state either improves:

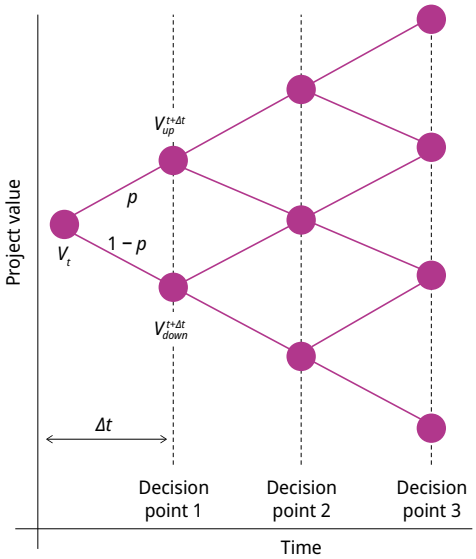
$$\left(V_{up}^{t+\Delta t}\right)$$

or deteriorates:

$$\left(V_{down}^{t+\Delta t}\right)$$

The tree branches out to new nodes as we move forwards in time toward an end state. The tree can be presented visually as shown in Figure 6.

Figure 6. Recombinant binomial tree expansion



$u = e^{\sigma\sqrt{\Delta t}}$

$d = \frac{1}{u}$

$p = \frac{e^{r\Delta t} - d}{u - d}$

u = step up multiplier
d = step down multiplier
σ = volatility of peak sales estimate (%)
Δt = time step
r = interest rate (%)
V_t = project value at time t
p = probability of up step
1-p = probability of down step

$$V_t = (1 + r)^{-dt}.P_t(p.V_{up}^{t+dt} + (1 - p).V_{down}^{t+dt}) + costs$$

In a financial option valuation setting, the binomial method is applied by starting at time zero and working forward to the next set of nodes to determine the value of the stock in the *up* and *down* scenarios. This process is repeated for the next time point, and then the next, until the lattice is complete (working from left to right in the diagram). Once the lattice of stock (share) valuations has been completed, the set of far-right nodes at the last time points is considered: from these values, it is possible to work back across the lattice (from right to left) to determine the value of the option. On reaching the node at time zero, the required information is found, which is the value of the option (rather than the stock, which is already known) at present. Applying this approach to a pharmaceutical development project is relatively complex, given the set of factors that need to be considered.

The initial project value (V_t) is typically the estimated peak sales for the product under development as this is currently estimated, and the starting point (t) is some point during the development of the project, such as the beginning of a clinical trial. Each decision point therefore corresponds to the end of a milestone (e.g., phase I trials) and the beginning of another (e.g., phase II trials). Additional time points can be added to allow for interim readouts or the potential for early termination. The results of the trials will either be successful and therefore correspond to an improvement in project value:

$$\left(V_{up}^{t+\Delta t}\right)$$

or conversely a deterioration:

$$\left(V_{down}^{t+\Delta t}\right)$$

To estimate the project up or down value we borrow from the world of finance using the formulae shown in Figure 6. The exponential term arises since, in the case of very small time steps, analytical and binomial solutions should converge.

We then determine the project value for each node up to the last decision point (decision point 3). At this point, we determine the discounted cash flows of compound sales up to peak sales, which is equivalent to an underlying stock in a financial options setting, and subsequently determine the rNPV for each node. Some nodes will likely yield a negative rNPV, e.g., due to failed clinical trials, suggesting that the project loses money. For these negative rNPVs we would abandon the project and equate the value to zero.

Once we have rNPV values for compound sales for each end node at the last decision point (decision point 3), we must now work our way back through each branch, to the previous time step (decision point 2) and calculate the rNPV of the project or the option, by analogy with financial options, for each node. In our calculations, we must apply the discount rate and

account for the probability of success for the stage of development. We repeat this exercise for all end nodes back to the initial state (V_t).

The use of real options can be confusing and it is necessary to carefully set out the options that are embedded into the project and to work through the valuation process systematically. The Chartered Financial Analyst Institute, which promotes financial analysis as a professional discipline, published a guide by Chance and Peterson (2002) that is one of the most accessible and practically oriented guides to the use of real options and this text is a valuable resource for developing a pragmatic understanding of real options valuation approaches.

Before proceeding with the pharmaceutical compound development case study, let us consider a different example to highlight the key elements of the binomial pricing approach. This case study is adapted, with different values, from a text by Moreira, [1] who has provided useful teaching materials.

Case study 3. Introductory example of the binomial pricing approach

A firm is planning to build a new factory to supply a product to the market. The NPV of the project, assessed using standard approaches, is USD 50 million. The managers at the firm believe that there is an option to expand the factory in two years at USD 15 million, if sales prove to be 40 percent more than initially anticipated, and as modeled in the NPV calculation. This is an expansion or growth option, which is analogous to a financial call option. The firm has the right, but not the obligation, to proceed with the factory expansion and will only do so if the value of the *underlying* – the project's NPV resulting from the project's cash flows – proves to be profitable, i.e., to exceed the cost of exercise, i.e., the expense of expanding the factory. The firm's managers are unable to estimate the probability of up and down moves in a binomial tree with any certainty but believe that the volatility of the project cash flows is 20 percent, based on market analysis. The interest rate is 5 percent. For simplicity, it is assumed that the factory was built rapidly at the start of the first time period.

This data allows a growth option to be specified as follows:

S = USD 50 million. This is the value of the underlying at time zero, i.e., the NPV of the project.

r = 0.05. This is the interest rate.

Δt = 1. There are two time periods in this example (each of one year).

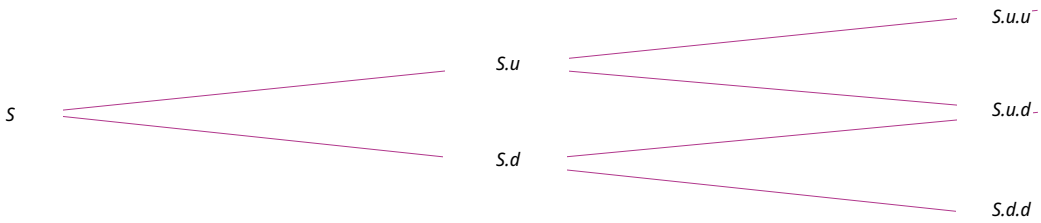
X = USD 15 million. The exercise price (i.e., the cost of the expansion) is USD 15 million.

σ = 20%. Volatility is assumed to be constant.

A binomial tree can be constructed in terms of the initial value of the underlying (S) and the up and down movement factors (u and d). The general form of this tree is shown in Figure 7. The values at the nodes are obtained by multiplying the initial value (S) by the relevant up and down multipliers for each specific node.

1 Examples of Real Options, H Moreira, 2023,

Figure 7. Calculation method – values of the underlying



As the firm's managers do not feel able to estimate the up and down probabilities in the decision tree, a risk-neutral valuation approach will be taken, with the formulae for calculating up and down movement probabilities applied, using the risk-free rate.

$u = e^{\sigma\sqrt{\Delta t}}$ Up step multiplier $d = \frac{1}{u}$ Down step multiplier $p = \frac{e^{r\Delta t} - d}{u - d}$ Probability of an up step

In this example, the values of the multipliers and the probability are as follows.

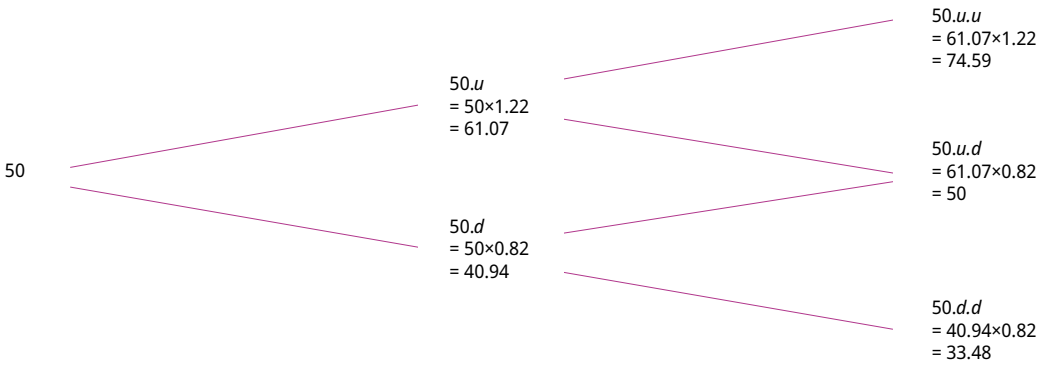
$u = 1.22$

$d = 0.82$

$p = 0.68$

Inserting the values provides the following binomial tree (Figure 8). This tree provides the values of the *underlying,* that is, the project, at the different time points in the different up (positive) and down (negative) scenarios.

Figure 8. Values of the underlying (the project)



Having worked from left to right across the diagram to find the values of the underlying at the different times and in the different scenarios, it is necessary to work from right to left to find the value of the option. To determine the value of the option itself, the value of the project and the option is calculated first. To start this process, the value of the project with the option can be determined at the end nodes of the base tree (Figure 8). At the top right node, for example, the value of the project and the option is the maximum of the value of the project and the value of the project plus the 40 percent growth in sales minus the exercise cost of the plant construction. The same percentage increase at each node may be an assumption that is reasonably valid in practice, given the difficulties of estimating potential future sales and the effect on project NPV. If desired, the general technique can be adapted to apply different estimates at the end nodes.

Value of the project plus option, at the top right-hand node = *Max* (74.59, 74.59(1.4) – 15)

The same approach can be applied to the other right-hand nodes. At the lowest node, the growth in sales does not raise the project's NPV sufficiently to justify the cost of plant construction, and so the option would not be exercised, i.e., the firm would not expand the plant.

To determine the values at each of the middle nodes, the following formula is applied, using the values at the immediately adjacent upper and lower nodes on the right-hand side, which relate to the next time period.

$$\text{Value at node} = \frac{[(\text{Value at the upper node} \times q) + (\text{Value at the lower node}) \times (1 - q)]}{e^{(r\sqrt{\Delta t})}}$$

Or, in different notation:

$$f_{i,j} = \frac{f_{i+j,j+1}.q + f_{1=i,j}.(1 - q)}{e^{(r.\sqrt{\Delta t}}}$$

where

$f_{i,j}$ = value at the node at time *i* and at (height) position *j* in the binomial lattice

and *q* is the term that relates up and down probabilities, as noted earlier.

For example, at the highest node for the 1-year, intermediate, time period, the value is calculated as follows.

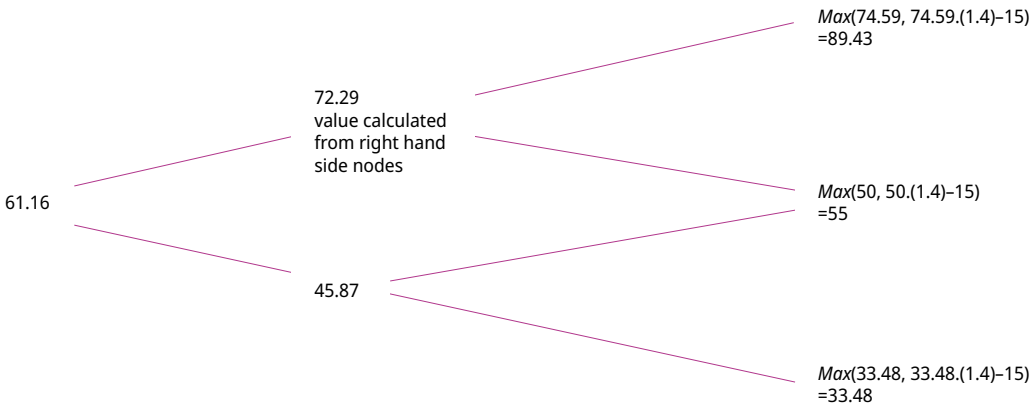
$$e^{(r.\sqrt{(\Delta t} = e^{((0.05)(1))} = 1.05$$

and the value at the node is:

$$f_{1,1} = \frac{(89.42(0.68) + 55.00(1 - 0.68)}{1.05} = 72.79$$

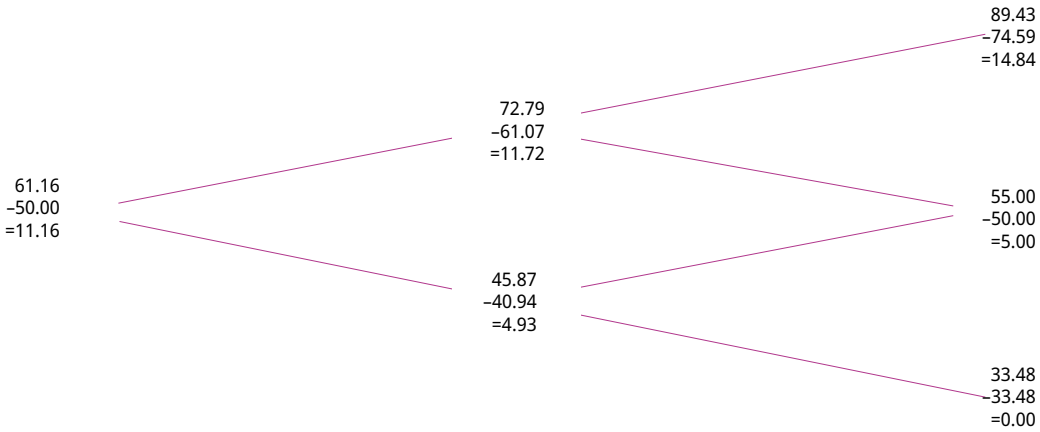
and the value at the node is: The value at the left-hand node, for time zero, is then calculated in the same fashion, using the previously determined values for the middle nodes. This provides the set of values as shown in Figure 9.

Figure 9. Values of the underlying and the option



As this resulting binomial tree is the set of values for the project *plus* the option, it is possible to determine the value of the option by subtracting the value of the project from the combined value at each node. This provides a tree that identifies the value of the option at different times and under different scenarios, as shown in Figure 10.

Figure 10. Values of the option



As would be expected, the value of the growth, or call, option is more valuable when the *underlying* is more valuable, i.e., the expansion option is valuable when sales are strong, and the option does not have any value, i.e., *out of money*, when sales are relatively weak, at the lowest right-hand node.

Importantly, the value of the project plus the expansion option exceeds the value of the project as calculated by NPV. The discounted cash flow approach does not consider the growth option that is known to management and embedded in the project. This is a limitation of the discounted cash flow approach and, consequently, NPV valuations may underestimate the true value of many projects. A key benefit of the real options method is to allow opportunities for managerial flexibility, such as this plant expansion option, to be included in the project evaluation and to be explicitly valued in financial terms.

Risk-neutral valuation

In general, certainty equivalent (risk-free) cash flows discounted at the risk-free rate, and financial options are valued using the risk-free rate, since a replicating portfolio is available and so risk-free arbitrage is possible. To apply this approach with real options, a replicating and tradeable portfolio is required, which is rarely available. Copeland and Antikarov (2001) propose a proxy financial security (e.g., publicly traded share) approach, but acknowledge the difficulties of this method.

In general, risky real-world projects should be valued using a risky rate. Application of this approach within a binomial decision tree structure requires probabilities to be known. In a corporate setting, it is often possible and desirable to develop a decision tree and to estimate the probabilities of up and down movements and the final state if the option is exercised, e.g., sales and project NPV in the event of a plant expansion. In this situation, a standard corporate discount rate would often be applied and a risky rate should be used. Some users adjust the discount rate to allow for risk as it is desirable to separate the effects of variation in future cash flows from the cost of capital and many firms will mandate the use of a standard (risky) rate in valuation activities, which reflects the cost of capital to the firm.

Case study 3 used the risk-free rate. Why was this the case? There is a relationship between the probabilities and the discount rate. If probabilities are not known, the standard approach is to use the risk-free rate and the risk-neutral probabilities. The values of p and $(1–p)$, the risk-neutral probabilities, are connected to the up and down factors (u and d) and the risk-free rate. For a given set of u and d, only one value of p is consistent with a specific risk-free rate. There are several sets of probabilities and risky (or risk-adjusted) rates that could be applied in the model; however, for a given risk-free rate, only one value of p is consistent with the values of u and d. In circumstances when the probabilities are not known and cannot be estimated, the use of the risk-neutral values provides a pragmatic pathway to estimating the value of the option.

Nonetheless, although this use of the risk-neutral probabilities in the binomial pricing method is a commonly adopted approach, it is important to recognize that the applicability of this approach is subject to legitimate theoretical challenges. For this approach to be truly valid, there must be a replicating tradeable portfolio available in a liquid market, enabling risk-free arbitrage. As discussed in the report, this is rarely the case for real options in corporate settings.

Despite this fact, the consensus of many users, developed over the past 30 years, has been that, if the binomial method rather than an equation-based analytical solution is used, the output from a real options valuation model is helpful, and, in many cases, is not overly sensitive to the exact value of the risk-free rate. This topic is discussed at length in the Chartered Financial Analyst Institute guide by Chance and Peterson (2002). Any user of risk-neutral valuation approaches should be aware of the theoretical challenges that can be made to this practice and of the constraints that the underpinning assumptions of option pricing impose.

In practice, the use of the firm's standard discount rate (cost of capital) and estimated probabilities, using a decision tree framework, provides a pragmatic approach to valuation. The real options method provides an alternative approach when these probabilities are not known and cannot be estimated with any reliability, but is subject to theoretical challenge, even when the binomial method is used.

Case study 4. Pharmaceutical compound development case study

The pharmaceutical case study will provide a realistic example to demonstrate this approach in practice. We will value the cystic fibrosis project using the real options valuation method using the following steps:

Step 1: Determine value drivers for the project

The first step before developing our decision tree is determining the most influential factors and input parameters. Assuming development goes as planned, we assume peak sales to be USD 420 million, with an annual volatility (σ) of 20 percent and a sales growth rate (μ) of 0 percent. From the discounted cash flow calculations earlier, we know the duration, cost and success rates of each development phase of the project. We will retain the discount rate of 10 percent and assume the operating margin is 75 percent. These project characteristics are summarized in Table 7.

Table 7. Project parameters and inputs for real options example

Project parameters	Inputs
Peak sales ($ millions)	$420
Discount rate (r)	10%
Time steps (years) (Δt)	1
Annual Volatility (σ) (uncertainty in peak sales)	20%
Estimated margin	75%
Time on market to peak sales (years)	10
Launch costs ($ millions)	50.00
Growth rate (μ)	0%

Source: Based on Bogdan and Villiger, 2020.

Let us briefly explore how each parameter can be determined:

- **Peak sales:** The estimation of peak sales involves conducting market research, analyzing comparable drugs in the market, and considering factors such as disease prevalence, potential market size, competition and pricing strategies. Market reports, industry experts, and historical sales data can provide valuable insights for estimating the potential revenue of the drug.
- **Discount rate (r):** The discount rate represents the cost of capital or the required rate of return. Typically, it is the firm's cost of capital, as discussed in the rNPV section; if this value is not available, a rate can be determined from industry standards or investor expectations. Published financial models, investment bank analyst reports and industry benchmarks are often used to establish an appropriate discount rate. When a risk-neutral valuation approach is being employed, the risk-free rate should be used.
- **Time steps (Δt):** Time steps refer to the length of each period in the decision tree model. The choice of time steps depends on the specific characteristics of the drug's development and market dynamics. Typically, shorter time steps are used for complex and rapidly changing markets, while longer time steps may be suitable for more stable markets.
- **Annual volatility (σ):** Annual volatility reflects the uncertainty or variability in the peak sales estimate. This parameter is determined by analyzing historical sales data of similar drugs, considering market dynamics, assessing the impact of potential factors such as regulatory changes or competition, and consulting industry experts. Statistical methods, such as calculating the standard deviation of past sales, can help estimate the annual volatility.
- **Estimated margin:** The estimated margin represents the profit margin or the percentage of revenue retained after deducting the costs of production, marketing and other expenses. It is typically determined based on industry benchmarks, cost structures, and profit projections. Financial analysis and expert insights are used to estimate the margin for the specific drug under evaluation.
- **Time on market to peak sales:** The time on the market to reach peak sales refers to the number of years from the drug's launch to when it is expected to achieve its maximum sales potential. This parameter is based on market research, historical data of similar drugs, the expected adoption rate and factors influencing market penetration and acceptance.
- **Launch costs:** Launch costs encompass the expenses incurred during the initial launch of the drug, including marketing, sales, distribution and regulatory compliance. These costs are estimated by considering industry benchmarks, the scope of the launch strategy, market entry requirements and anticipated resource needs.
- **Growth rate (μ):** The growth rate represents the expected rate of sales growth after product launch toward peak sales. It can be influenced by factors such as market saturation, competition, new indications or markets and lifecycle management strategies. Market analysis, industry forecasts and expert opinions can inform the estimation of the growth rate.

It is important to note that these parameters are subject to uncertainty, and different scenarios and sensitivity analyses may be conducted to understand the impact of variations in the parameter values on the valuation outcomes. In particular, given the importance of volatility in option calculations, care should be taken to assess this value carefully and to explore the sensitivity of this input on the output values.

Step 2: Span the decision tree

Using these data and the formulae shown in Table 7 we can determine that for the CF project, u = 1.22, d = 0.82, p = 45 percent and (1–p) = 55 percent. We can now span the tree, following the approach used by Bogdan and Villiger (2010) as shown in Table 8.

Table 8. Binomial tree displaying market states for the cystic fibrosis project

Stage of development	Phase I	Phase I1	Phase II	Phase II1	Phase III	Phase III1	Phase III2	Approval
Project year	1	2	3	4	5	6	7	8
								1,703
							1,394	0.4%
						1,142	0.8%	1,142
					935	1.8%	935	3.2%
				765	4.1%	765	6.1%	765
			627	9.1%	627	11.3%	627	11.7%
		513	20.3%	513	20.1%	513	18.6%	513
	420	45%	420	33.4%	420	27.6%	420	23.9%
	100%	344	49.5%	344	36.8%	344	30.3%	344
		55%	282	40.8%	282	33.7%	282	29.2%
			30.2%	231	29.9%	231	27.8%	231
				16.6%	189	20.6%	189	21.4%
					9.1%	155	13.6%	155
		Peak sales (USD million)			5.0%	127	8.7%	127
		Probability				2.8%	104	5.5%
								1.5%

Source: Based on Bogdan and Villiger, 2020

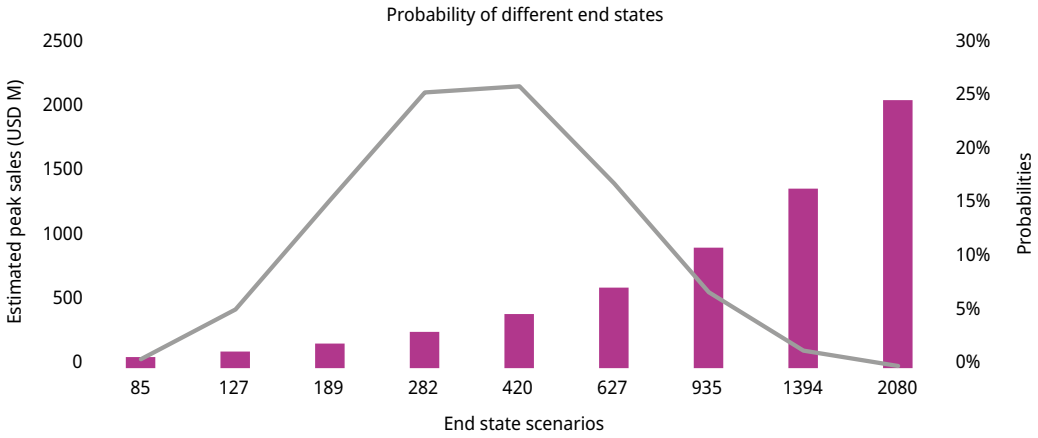
The Bogdan and Villiger approach spans a binomial tree for the peak sales estimate, which is determined by first developing an rNPV of the drug candidate and determining when peak sales are likely to occur. By incorporating the peak sales estimate as the starting point, the decision tree captures the potential upside and the subsequent strategic decisions that may influence the drug's success and financial outcomes. Our drug candidate is indeed in its early clinical trial phase and the actual peak sales are uncertain. The decision tree allows for the exploration of different scenarios and decision points throughout the drug's development lifecycle. It considers the potential risks, uncertainties and strategic choices that may impact the ultimate success and value of the drug.

The decision tree branches out at each decision point, considering factors such as trial results, regulatory approvals, market conditions and competitive landscape. By quantifying these factors probabilistically and incorporating the estimated peak sales, the decision tree provides insights into the value of the drug candidate under different possible outcomes. The goal of developing a decision tree in this way is to enable a more comprehensive analysis of the drug candidate's value, incorporating both the uncertainty of its development path and the potential strategic decisions that can shape its future success. It provides a structured framework to assess the financial implications of different investment choices and helps stakeholders make informed decisions regarding resource allocation, licensing agreements or further development strategies

From Table 7, we estimate that there is a possibility of making up to USD 2,080 million in peak sales (at the highest value end node). However, this scenario is only likely to occur with a probability of 0.2 percent, which suggests that it is highly unlikely. Conversely, our most probable estimates are USD 420 million with a probability of 26.3 percent, and USD 282 million, with a probability of 25.7 percent. We also observe that for each node in a particular time step (each column) the probabilities add up to 100 percent. For this project, there are three decision points: the beginning of phase II, the beginning of phase III and the approval stage.

The probability of each end state is illustrated in Figure 11.

Figure 11. Probabilities of different end states for the cystic fibrosis project



Source: Based on Bogdan and Villiger, 2010

In analyzing the end states of our decision tree, we have uncovered a wide range of potential outcomes for the peak sales estimates of our drug candidate. This range spans from a high estimate of USD 2,080 million to a low estimate of USD 85 million. Within this spectrum, two key end states appear to be the most probable: USD 420 million and USD 282 million. These findings provide valuable insights into the financial performance of our drug candidate under different scenarios. The varying outcomes reflect the inherent uncertainties and risks involved in drug development, considering factors such as clinical trial results, regulatory approvals, market dynamics and competition.

The significance of these results lies in their implications for decision-making and strategic planning. By understanding the range of potential outcomes, we gain a clearer understanding of the risk-reward trade-offs associated with different development strategies, licensing agreements and resource allocations. This knowledge allows us to make more informed decisions about the optimal path to pursue.

Importantly, the analysis of end states demonstrates the value of utilizing a decision tree framework. It provides a structured approach for evaluating the potential financial outcomes of different strategic choices, enabling us to navigate the uncertainties inherent in early-stage biotechnology valuation. This comprehensive evaluation supports strategic planning, facilitates resource optimization and ultimately assists in maximizing the potential of your drug candidate.

Step 3: Calculate the rNPV of each end state

Once we have modeled the tree to the market entry stage, for the underlying (the peak sales of the drug), we use these peak sales estimates to develop the discounted cash flow of the project, to undertake the development of the compound and sum these up to determine the rNPV of the project/option for each node (Table 9).

Table 9. rNPV estimation of highest value end node for the cystic fibrosis project

Discounting	100%	91%	83%	76%	70%	64%	58%	53%	48%	44%
Sales (USD M)	2,080	2,080	2,080	2,080	2,080	2,080	2,080	2,080	2,080	2,080
Operating profit (USD M)	1,560	1,560	1,560	1,560	1,560	1,560	1,560	1,560	1,560	1,560
DCF	1,560	1,425	1,301	1,188	1,085	991	905	827	755	689
rNPV (USD M)	**10,727**									

We then repeat this exercise for each end node to yield the rNPV values shown in Table 10.

Table 10. rNPV for each end state at the market entry point

Peak sales estimate at end node (USD M)	2,080	1,394	935	627	420	282	189	127	85
Probability of occurring (%)	0.20%	1.60%	7.00%	17.20%	26.30%	25.70%	15.70%	5.50%	0.80%
rNPV (USD M)	10,727	7,190	4,820	3,231	2,166	1,452	973	652	437

Step 4: Extend the solution to the previous phases of the project

Now that we have the value of the end states of the option value, i.e., the value of undertaking the drug development project, we can work our way back through the tree to the previous time step (last year of phase III) to determine the rNPV during the development of the CF project and the value of the option at each node. In our calculations, we must account for the success rates of each phase and discount the values appropriately using the formula in Equation 5.

Equation 5. Calculation of project value

$$V_t = (1 + r)^{-dt} . P_t \left(p.V_{up}^{t+dt} + (1 - p). V_{down}^{t+dt} \right) - costs$$

These calculations yield the values in Table 11.

Table 11. Solving the tree to determine project value at the initial market state

Stage of development	Phases I	I1	II	II1	III	III1	III2	Approval	Sales
Project year	1	2	3	4	5	6	7	8	9
									2
								2	11
							1	7	1
						1	4	1	7
					935	3	935	5	935
				765	2	765	3	765	5
			627	709	627	2	627	3	627
		513	524	513	2	513	2	513	3
	420	232	420	471	420	1	420	2	420
	170	344	346	344	1	344	1	344	2
		152	282	312	282	956	282	1	282
			227	231	704	231	862	231	1
				205	189	635	189	975	189
					464	155	575	155	973
						420	127	653	127
							382	104	652
								437	85
									437

When calculating the rNPV for each end state on a decision tree and extending the solution to previous phases of the project, several sanity checks can be conducted to ensure the accuracy and reliability of the results. These sanity checks serve as validation measures and help assess the reasonableness of the calculated values. Here are some common sanity checks:

- **Sensitivity analysis:** Varying key parameters, such as peak sales, discount rate, development costs or time frames, allows for an examination of how changes in these variables impact the rNPV. It helps identify which factors have the most significant influence on the valuation and can highlight areas of uncertainty or sensitivity.
- **Comparison to historical data:** Comparing the calculated rNPV with similar past projects or industry benchmarks can provide a reference point for evaluation. If the calculated values deviate significantly from historical data, it may indicate the need for further scrutiny or reassessment of underlying assumptions.
- **Expert judgment:** Seeking input from domain experts, such as experienced biotechnology professionals, industry consultants or advisers, can help validate the reasonableness of the rNPV estimates. Expert opinions can provide valuable insights into the specific dynamics and risks associated with the biotechnology sector.
- **Consistency with market expectations:** Assessing whether the calculated rNPV aligns with market expectations, investor perspectives or industry trends can serve as a reality check. If the valuation seems significantly out of line with prevailing market conditions or investor sentiment, it may warrant a reassessment of the inputs or underlying assumptions.

The contribution of conducting these sanity checks is to enhance the credibility and robustness of the valuation analysis. It helps identify potential errors, biases or inconsistencies in the

model and allows for adjustments or refinements to be made. By incorporating various validation measures, decision-makers can have greater confidence in the rNPV results and use them as a basis for strategic decision-making, resource allocation or investment evaluations. Ultimately, this method helps in assessing the potential value and risk of early-stage biotechnology IP assets, facilitating informed choices and maximizing the value of the projects.

The approach that is detailed here is comprehensive and requires significant data gathering and computational effort. In other circumstances, for example in some technology licensing scenarios, a simpler assessment of the situation at each node may be adequate to develop a helpful model and to provide a financial value of the project. The binomial pricing method is flexible, adaptable to several option scenarios, and relatively transparent to the users of the end data; it provides a robust approach to valuing real options and can be used in a rigorous and complex fashion, as in this example, or in a more straightforward manner, depending on the situation.

Considerations when using real options

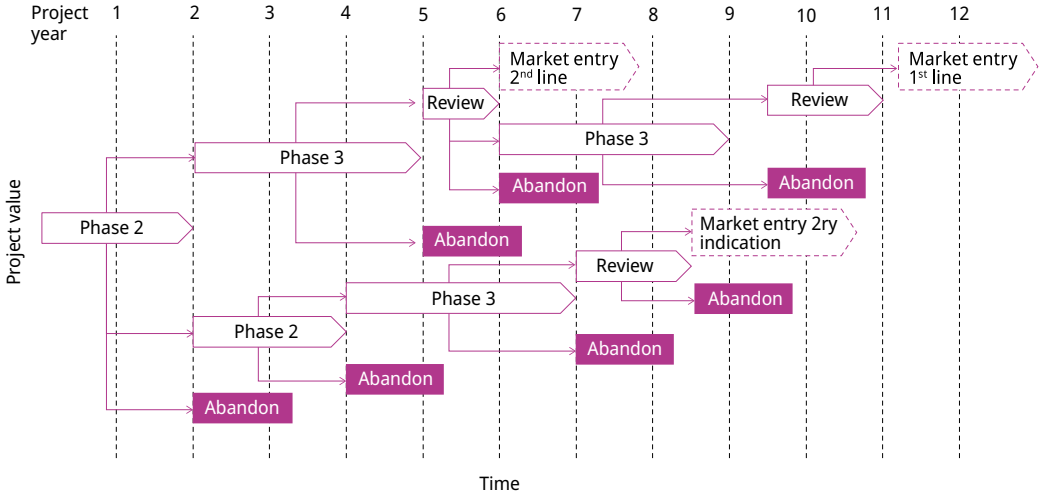
As mentioned earlier, the binary nature of drug development trials (success or failure) may mask other outcomes, which present project managers with a range of options to explore. For instance, clinical trial results may be overwhelmingly positive, triggering the expected next phase of trials. Conversely, they may fail from a safety or efficacy perspective in which case the project is abandoned. However, there are situations where the hypothesis under investigation is not proven by the data, but the researchers think that a redesign and refinement may be sufficient to run additional trials. Let us use a simple example to illustrate these points.

Illustration using real options

The CEO of BioTech would like to raise investment for her company to fund their flagship pipeline project, TumaBlok. She needs to articulate the value proposition to potential investors. The CEO decides to perform a valuation using the real options valuation method. TumaBlok is entering phase II and is a second line[2] treatment for renal cancer. She expects that TumaBlok will be used in combination with other treatment options. By reviewing both historical data and established industry practice, the CEO expects that the outcome of phase II trials are such that some are successful, and the drug proceeds to phase III; in others, the trial fails and the project is abandoned. However, there is an additional outcome, where the trial results may indicate efficacy in other similar indications involving the treatment of solid tumors such as lung and breast cancer. In this latter case, she expects that a second phase II trial will be approved to focus on the secondary indication. In the first indication (renal cancer), the expectation is that successful phase III trials will lead to a review and approval phase, which if successful allows the drug to enter the market as a second line treatment. During review, there is an option to conduct a second phase III trial, to determine whether TumaBlok could be used as a first line treatment. If all goes well, the first line treatment will enter the market sometime after the second line is approved. The CEO decides to map out a decision tree for the project and resolve it for the range of viable scenarios as shown in Figure 12.

2 Treatment for a disease that is administered after initial/preferred treatment (1st line) stops working or fails.

Figure 12: Decision tree for TumaBlok showing the range of viable options available



Source: Author based on Bogdan and Villiger, 2010.

In Figure 12, the red time steps (2, 4, 5, 6, 7, 8, 9 and 11) represent decision points for the project. The CEO would have to resolve each tree to estimate the project value at the start of the outset (year 1) for the complex TumaBlok decision tree. The CEO's calculations must be based on defensible assumptions for peak sales estimates, growth rates and attrition levels during development for all products. These values must be sourced from well-established industry averages, sales values for similar drugs on the market and against comparable companies to BioTech in terms of profile (size and portfolio). The CEO must also be aware that the duration of trials may be longer than expected and consequently, may cost more. She must adapt her calculations accordingly. This example shows that the decision tree can be complex and may require careful resolution to ensure that all viable options are appropriately treated. For companies with several projects in their pipelines dedicated valuation tools and resources may be necessary to elucidate the value of individual projects and entire portfolios.

Industry experience in using real options – benefits and challenges

Many valuation experts believe that real options provides the closest approach to the *economic truth* of the set of techniques that are reviewed in this guide. The explicit consideration of growth and termination options is useful and can help frame insightful discussions internally and provide a framework for articulating the value of an asset or a technology in a negotiation setting. However, real options analysis relies on complicated techniques and is unfamiliar to many people, including many senior managers in the biotechnology and pharmaceutical industries. The inclusion of growth options can lead to values that exceed those generated by NPV approaches and to rigorous questioning, hence the suggestion in this guide to apply the binomial approach. In the pharmaceutical industry, the fact that rNPV is a well-understood approach has led to its dominance, although many firms have at least in some situations used real options valuation approaches over the past 10 to 15 years. The real options method has some challenges but also great potential, and its use is likely to increase over the next decade.

Conclusions

IP valuation in the biotechnology and life sciences field is a dynamic and exciting endeavor that empowers innovation professionals to unlock the value of their IP assets. By utilizing various valuation methods, including the income-based approaches and the market approach, professionals can gain valuable insights into the worth of their innovations and make informed decisions.

This publication aims to demystify IP valuation in biotechnology and life sciences and equip those new to the field, as well as professionals working in universities, spinouts and small- and medium-sized businesses, with the tools and knowledge to navigate the valuation process. By understanding the popular methods and following the practical guidance provided, innovation professionals can confidently approach IP valuation and maximize the value of their assets.

While the valuation process may involve challenges and uncertainties, it also presents tremendous opportunities for growth and collaboration. The valuation exercise allows professionals to explore the potential of their IP, attract strategic partnerships, secure funding and drive innovation forward. It empowers them to showcase the value of their ground-breaking ideas and make a meaningful impact in the biotechnology and life sciences landscape.

As the field continues to evolve, it is important to stay informed about emerging trends, market dynamics, and best practices in IP valuation. By leveraging the expertise of valuation professionals, collaborating with industry peers and continuously updating valuation models with relevant data, professionals can stay at the forefront of valuation practices and ensure their decisions align with the changing landscape.

Remember, the journey of IP valuation is not just about numbers and figures. It is a pathway to unlocking the transformative potential of innovation. It is about realizing the value of ideas that can revolutionize patient care, improve lives, and shape the future of health care. By embracing IP valuation as a powerful tool, innovation professionals can drive positive change, foster collaborations, and ultimately bring their innovative solutions to the world.

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Intellectual Property Valuation in Biotechnology and Pharmaceuticals delves into advanced valuation methods such as risk-adjusted NPV and real options analysis, tailored to the unique dynamics of the biotechnology and pharmaceutical sectors. Using case study examples, the guide explores the multi-stage development process, providing tools to evaluate licensing, milestones and market exclusivity scenarios effectively.

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