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Making Growth Happen.

Guiding Principles in Biotech Valuation

Contents

1.0 Introduction

Overview

This report provides a detailed examination of how institutional and strategic investors assess the value of biotechnology companies. While multiple valuation approaches are used across the life sciences sector, our analysis shows that specialised biotech investors and major pharmaceutical firms predominantly apply the **Risk-Adjusted Net Present Value (rNPV)** framework to guide investment and acquisition decisions.

How rNPV Works

- Combines financial projections with probabilistic assessments of scientific and regulatory risk.
- Forecasts expected future net cash flows from a therapeutic candidate over its commercial lifecycle.
- Adjusts these projections for probability of success at each stage of research, development, and regulatory approval.
- Applies a discount rate to convert risk-adjusted cash flows into present value, quantifying the therapy's economic potential.

rNPV captures both financial and technical uncertainty, making it the standard tool for biotech valuation

Benefits of rNPV

By integrating rigorous financial analysis with probabilistic modelling of technical, clinical, and regulatory risk, the rNPV framework allows investors to make data-driven decisions regarding portfolio allocation, partnerships, and long-term value creation in the biotechnology sector.

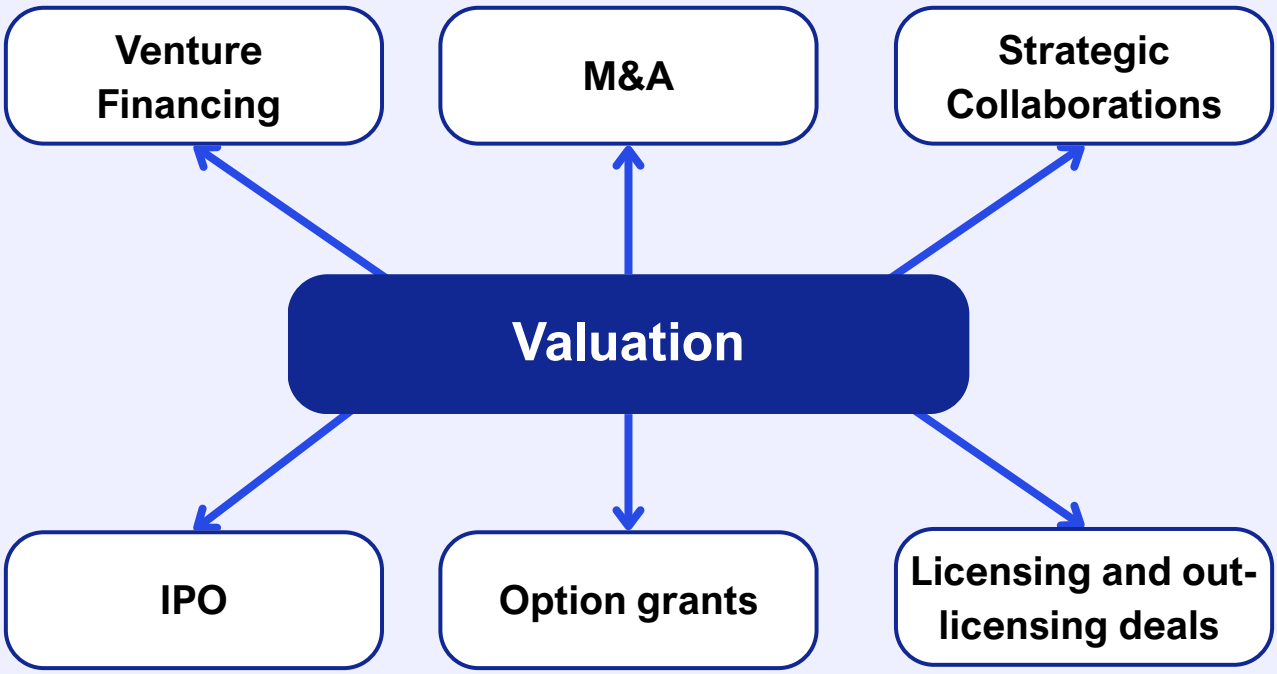
01	**Net cash flows:** Total cash generated or consumed by a company and calculated by: **Net Cash Flow = Revenue - Expenses + Other Cash Flows** Revenue projections for biotechnology candidates are typically based on potential patient populations, expected uptake, and therapy pricing, or on the broader market opportunity and likely product share. Key expenses include research and development—often substantial due to preclinical and clinical trials—manufacturing, and selling, general, and administrative costs. Additional cash flows account for changes in working capital, taxes, and other operational factors.
02	**Risk Weighting Adjustments:** Future cash flows are adjusted for the probability of success at each development stage, including preclinical research, clinical trials, and regulatory approval. These risk-weighted adjustments account for scientific, technical, and regulatory uncertainties, while factors such as market adoption, competition, and potential delays provide a realistic, risk-adjusted estimate of a therapy's expected value.
03	**Discount Rate:** The discount rate captures the overall risk profile of biotechnology and drug development companies, incorporating factors such as financing structure, manufacturing capabilities, management effectiveness, and intellectual property considerations.

2.0 Unlocking the Value of Biotech Companies

This report aims to provide a structured framework for valuing biotechnology companies and to highlight why rigorous valuation is critical for long-term strategic success.

Valuation serves as a disciplined process for quantifying the economic potential of a biotech enterprise and its proprietary therapies or platforms. It informs key corporate decisions by providing a clear view of financial performance, growth potential, and competitive positioning. A robust valuation framework aligns the expectations of investors and management, supports confidence in strategic negotiations, and guides forward-looking investment and development decisions.

Accurate valuation is particularly essential at critical stages of a biotech company's lifecycle, including venture financing, mergers and acquisitions, strategic collaborations, initial public offerings, internal capital allocation, and the structuring of employee equity incentives.



3.0 Valuation Methods

3.1 Risk-Adjusted Net Present Value (rNPV) method

Definition

The **Risk-Adjusted Net Present Value (rNPV)** approach is the predominant valuation method used in the biotechnology sector. It represents best practice for assessing high-risk, innovation-driven assets such as drug candidates. The method provides a more sophisticated framework than traditional valuation models by explicitly incorporating the probability of success at each stage of development.

Purpose

When valuing biotechnology assets, investors seek to forecast future cash flows while accounting for the inherent uncertainties of clinical trials, regulatory approval, and commercialisation. The rNPV method achieves this by adapting the classical Discounted Cash Flow (DCF) model: future revenues and costs are projected to derive a present value, but each stage's cash flows are adjusted according to its respective probability of technical and regulatory success.

Comparison to Conventional DCF

Traditional DCF	rNPV Approach
Assumes deterministic cash flows.	Introduces **phase-specific risk adjustments** reflecting regulatory attrition rates.
Suitable for established firms with predictable earnings.	Designed for **high-risk R&D assets** with uncertain outcomes
Applies a uniform discount rate.	Incorporates **probability-weighted adjustments** across development stages.

As such, it is not simply an alternative method—it is considered the industry gold standard for valuing biotechnology assets [1].

Supporting Literature

As noted by Frei et al. (2016), the objective of the rNPV approach is to estimate future cash flows, adjust them for development and regulatory risk, and discount them to present value. Frei and Leleux (2004) emphasised that a company's value ultimately resides in its ability to generate future profits, making valuation inherently speculative [2]. They advocate a rigorous process combining primary valuation (projected free cash flows and cost of capital) with secondary valuation (market comparables).

Practical Application

In practice, entrepreneurs and analysts use rNPV to assess potential revenues, expected time to market, and development risks. By quantifying these uncertainties, rNPV enables investors and acquirers to evaluate the fair value of early-stage technologies, licensing opportunities, or acquisition targets [3].

3.1 Risk-Adjusted Net Present Value (rNPV) method

Industry Endorsement

The BIO Advanced Business Development Course (2015) confirms that income-based valuation models—specifically DCF and NPV variants—are widely used across the life sciences sector, and that risk-adjusting these models is essential for credible deal structuring. The course notes that buyers involved in preclinical or clinical-stage transactions predominantly employ rNPV as their valuation standard.

Industry Methodology

Given the uncertainty inherent in drug development [4][5], the prevailing methodology in the industry revolves around refinements of the traditional NPV framework, with **rNPV being the most widely adopted variant** [6]. As **Aswath Damodaran** highlights in The Dark Side of Valuation (2009), decision tree modelling can complement rNPV by explicitly capturing sequential, binary risks such as FDA approval outcomes.

A 2018 survey by the **Licensing Executives Society (U.S.A. & Canada)** encompassing 314 global transactions found that:

83% of large pharmaceutical companies relied on NPV or rNPV

as their primary valuation tool—underscoring the dominance of present-value-based methodologies in biotechnology [7].

Why rNPV is Preferred

rNPV remains the preferred approach for valuing biotechnology assets at all stages of development because:

- It explicitly adjusts for development risk using stage-specific probabilities of success.
- It reflects the economic logic underpinning rational investment decisions in high-risk R&D ventures.
- It is the standard model employed by major pharmaceutical companies, venture capital firms, and industry analysts.

Academic & Industry Authority

Further reinforcing its authority, AusBiotech's Guide to Life Sciences Investing (2018) identifies rNPV as the most appropriate valuation methodology for capturing the risk and potential of development-stage biotechnology assets. The guide recognises market comparables only as a secondary "sanity check" and does not endorse cost-based valuation methods [8].

A 2022 collaborative report by the University of Sydney and AusBiotech, referred to as the "Gold Standard" framework, further validates rNPV as the cornerstone of biotech valuation. The report emphasises that each project represents a unique value proposition shaped by multiple factors—such as target market, clinical profile, competitive landscape, development cost and timing, and phase-specific probabilities of success. It concludes that the rNPV framework offers the most robust basis for valuing early-stage intellectual property, negotiating commercial licensing, and structuring royalties [9].

3.2 Market Comparables and Transaction Analysis

Market-Based Approaches Explained

Market-based valuation approaches, which analyse comparable transactions, equity valuations, or the market capitalisations of similar firms, serve as a useful cross-check in biotechnology valuation. The sector records thousands of transactions annually, including licensing deals, R&D collaborations, and capital raisings (e.g., private placements, IPOs).

Key Considerations

However, meaningful comparison requires that the transaction involve a clearly defined unit of intellectual property (IP) or platform technology closely resembling the subject asset. This is particularly relevant when valuing a company focused on a single therapeutic or technological domain.

Due to data limitations and the proprietary nature of early-stage deals, suitable comparables are often difficult to obtain. Consequently, market-based analyses are typically used to support or benchmark values derived from rNPV or DCF models rather than to replace them.

Limitations

This method operates on the assumption that similar assets should exhibit similar values, yet its accuracy is constrained by:

- The limited availability of comparable deals at similar stages of development; and
- The non-disclosure of key terms in private or early-stage transactions [10].

References:
[1] Frei, P., & Peire, A. (2016). What is the value of a deal? Nature Biopharma Dealmakers, B27–B28.
[2] Frei, P., & Leleux, B. (2004). Valuation – What you need to know. Nature Biotechnology
[3] Stewart, J. J., Allison, P. N., & Johnson, R. S. (2001). Putting a price on biotechnology. Nature Biotechnology
[4] Dixit, A. K., & Pindyck, R. S. (1994). Investment under uncertainty. Princeton University Press, pp. 46.
[5] Schwartz, E. S., & Trigeorgis, L. (2004). Real options and investment under uncertainty: Classical readings and recent contributions. MIT Press.
[6] Svennebring, A. M., & Wikberg, J. E. S. (2013). Net present value approaches for drug discovery. SpringerPlus.
[7] Licensing Executives Society (U.S.A. and Canada). (2018). Global “life sciences” royalty rates & deal terms survey, pp. 107, 111
[8] AusBiotech. (2018), Guide to Life Sciences Investing, pp. 31-34
[9] AusBiotech. (2022). ‘Gold standard’ commercialisation for biotech.
[10] Gryphon Analytics – Pharma & Biotech Development & Valuation (2013)

4.0 Valuation Process

For evaluating drug development projects, the Risk-Adjusted NPV (rNPV) method is the standard valuation tool.

The rNPV can be calculated using the following formula:

Revenues	—	Costs	—	Other Cash Outflows
Total Market Prescriptions Written × Penetration of Product × Units Sold × Price = Revenue		COGS + Research and Development Expense + Selling Costs + G&A / Other Costs + Acquisition Costs		Capital Expenditure + Change in Working Capital − Cash Taxes

=

Net Cash Flows

$$rNPV = \sum_{t=1}^{N} \frac{R_1 C_t}{(1+r)^t}$$

Where

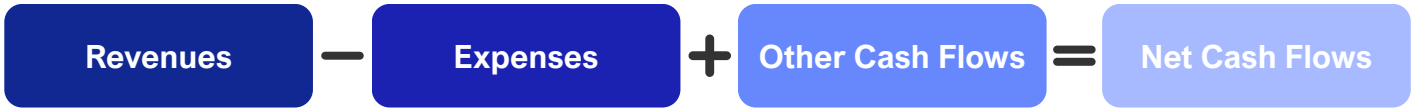
N = Number of Years
t = year
t = 1 (present)
C = cash flow
R_1 = Probability of cash flow now
r = discount rate

However, this process can be broken into three steps, outlined in the following diagram:

1. Project the anticipated net cash flows from the biotech program
2. Weight the projected cash flows according to assessed risk levels
3. Apply the annual discount rate to the risk-adjusted future cash flows

4.1 Estimating Net Cashflows

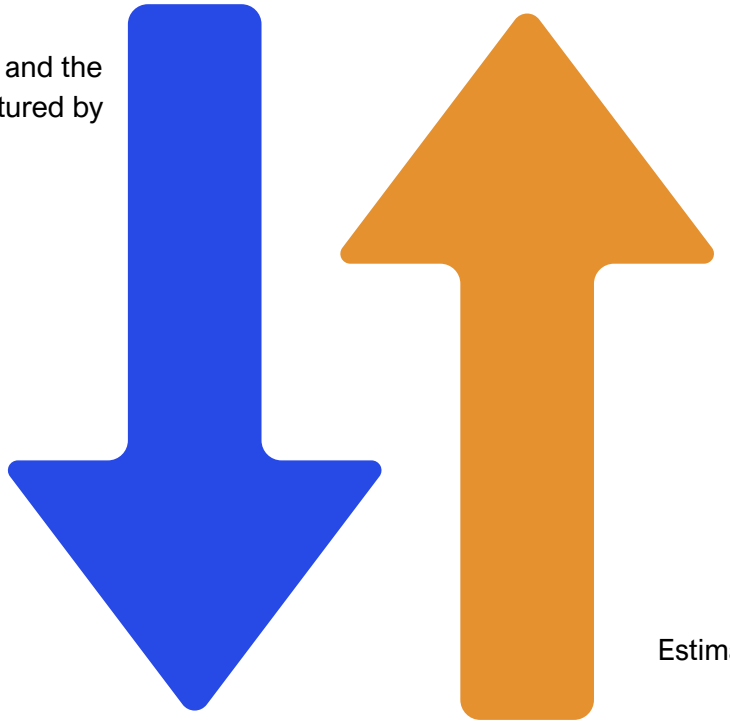
Net Cash Flows
Net cash flows are determined by subtracting expenses from revenue and adding other cash inflows.



Sales Pattern
Sales generally begin to appear about 12 years after R&D completion. They typically peak during the patent-protected period following launch and early market penetration (about three to four years). After a few years at peak levels, sales decline as competing products enter the market. Once patent protection ends, generics emerge and sales eventually cease.

Revenue Estimation Approaches
Two main methods are used to forecast drug revenues:

Top-Down
Estimate total market size and the share expected to be captured by the drug.



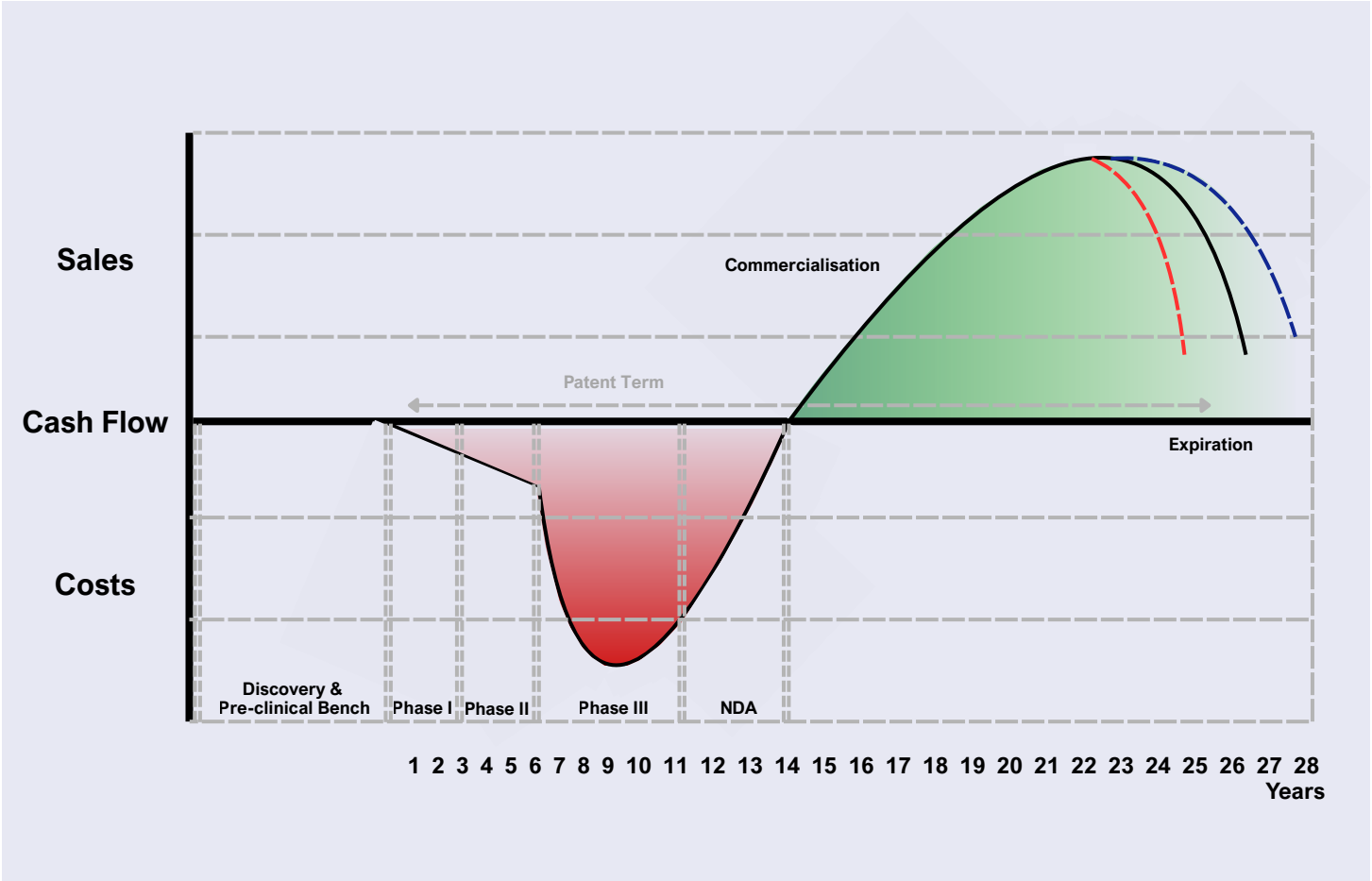
Bottom-Up
Estimate the patient numbers and price per treatment

4.1 Estimating Net Cashflows

Expenses
Costs include R&D (incurred during the first 12 years) and post-approval costs such as manufacturing (typically 33% of sales) and SG&A (about 25% of sales).

Other Cash Flows
Additional items included changes in working capital, cash taxes, and similar adjustments.

Cash Flow Outlook for a Marketed Drug



4.1.1 Revenue

Two main approaches are used to estimate revenues:

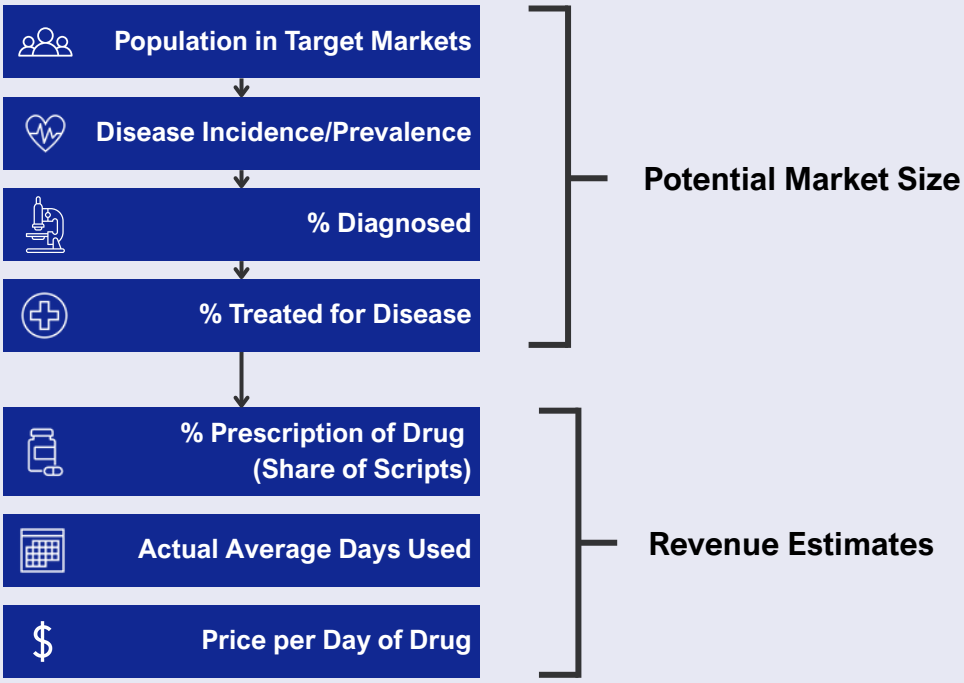
1. Bottom-Up Approach

This method starts with the patient population. Two key measures are used:

- **Incidence**: The number of new patients each year. Best suited for products that address a one-off acute condition (e.g., heart attack).
- **Prevalence**: The total number of patients at a given time. Most relevant for products requiring ongoing or repeat purchases by the same patients (e.g., chronic prescription therapies).

Revenue is then derived using the following calculation:

Revenue = Total Patient Population × Expected Market Share × Monthly Drug Price × Average treatment duration (months)



2. Top-Down Approach

This method begins with the overall size of the target market. The potential revenue is derived by estimating:

Total Market Value	The share the product is likely to capture	The expected growth rate.

Key factors influencing market share including product pricing, competitive landscape, relative advantages versus existing treatments, and the historical adoption of comparable products.

4.1.2 R&D Costs

R&D Stages

Calculating R&D expenditure begins with an assessment of the drug development pathway, as summarised in the table below.

Drug development stages

	Early Stage		Clinical Development				
	Discovery	**Pre-clinical**	**Phase I**	**Phase II**	**Phase III**	**Regulatory Review**	**Market Launch**
Time			1-2 years	1-2 years	1-2 years	1-2 years	
Typical Population	Laboratory studies	Laboratory and animal studies	20 to 80 healthy volunteers	100-300 patient volunteers	1000-3000 patient volunteers		
Purpose	Discovery and synthesis of drug candidate	Assess safety and efficacy profile	Establish safe dosages and assess absorption, distribution, metabolic effects and excretion and toxicity of candidate	Test drug candidate in patients with targeted disease/ condition. Verify safety and obtain preliminary efficacy data. Phase II can be divided into Phase IIA and Phase IIB. Phase IIA is designed to assess dosing requirements whereas Phase IIB is designed to study efficacy	Establish statistically efficacy and monitor adverse reactions that occur infrequently. Preparation for market launch (including sales force construction) can start in Phase III.	Obtain marketing approval in major markets.	Launch commercial sales of drugs.

4.1.2 R&D Costs

R&D Period

As illustrated in the table below, the average drug development timeline is approximately 12 years. Because patent protection is typically secured at the commencement of clinical development and standard patent terms extend for 20 years, the effective period of market exclusivity is reduced to roughly 8 years post-commercial approval. This exclusivity window may be further influenced by factors such as regulatory data protection, supplementary protection certificates, and potential patent term extensions.

	Period (Months)					
STUDY	**Preclinical**	**Phase I**	**Phase II**	**Phase III**	**FDA**	**TOTAL**
DiMasi et al (1991)	-	16	23	30	-	
DiMasi et al (2003)	-	22	26	31	-	
Abrantes-Metz, Adams	-	20	25	41	-	
Adams and Brantner	-	19	30	30	-	
DiMasi & Grabowski	52	20	29	33	16	
Bogdan & Villiger	41	20	26	30	18	
Adams and Brantner	-	17	31	27	-	
Paul et al (2010)	-	18	30	30	-	
Bloeme, Jansen, Krul	66	32	44	37	10	
Average (Months)	**53**	**20**	**29**	**32**	**15**	**149**
Average (Years)	***4.4***	***1.7***	***2.4***	***2.7***	***1.2***	***12***

4.1.2 R&D Costs

R&D Costs

The average out-of-pocket R&D expenditure required to bring a drug to market is estimated at approximately US$790 million. A stage-by-stage breakdown of these costs across the clinical development pathway is provided in the table below:

Drug Out-Of-Pocket Costs (USD millions)

Average Out-Of-Pocket Cost (USD millions)						
STUDY	**Preclinical**	**Phase I**	**Phase II**	**Phase III**	**Post-Approval**	**TOTAL**
DiMasi et al (1991)	-	4	8	25	-	
DiMasi et al (2003)	-	20	30	111	-	
Paul et al (2010)	-	16	42	158	-	
Adams, Brantner	-	31	111	78	-	
Mestre-Ferrandiz,	-	23	54	129	-	
DiMasi, Grabowski,	430	25	59	255	466	
Wouters, McKee,	238	53	101	292	-	
Bloeme, Jansen, Krul	30	14	140	38	195	
Average	**233**	**23**	**68**	**136**	**331**	**790**

Pre-clinical expenditures are highly variable, as they depend on the speed of identifying viable lead compounds and their responsiveness to early-stage testing. By contrast, Phase III trials follow a more standardised and rigorous protocol, but represent one of the most costly stages of development due to the requirement for large patient cohorts.

4.1.3 Post-Approval Costs

Post-Approval Costs

Post-approval production costs are directly linked to sales and tend to fluctuate accordingly. On average, production costs represent approximately 29% of sales, reflecting the cost of goods sold (COGS) margins typical among leading pharmaceutical companies.

Sales, General, and Administrative (SG&A) expenses, which primarily cover marketing activities and, to a lesser extent, ongoing safety profile testing post- launch, average around 27% of revenues, based on SG&A margins in the industry.

COGS and SGA Margins of Leading Pharma Companies

Company	COGS Margin 2024	SGA Margin 2024
Abbvie	30%	26%
AstraZeneca	19%	37%
Bristol Myers Squibb	29%	17%
GlaxoSmithKline	29%	35%
Johnson & Johnson	31%	26%
Merck	41%	28%
Novartis	25%	25%
Pfizer	29%	24%
Roche	26%	24%
Mean	**29%**	**27%**

(Source: Company Financial Reports)

4.2 Risk Weightings Adjustment

Probability of R&D Success

The overall probability of clinical success—defined as the likelihood that a candidate entering Phase I trials ultimately obtains regulatory approval—is estimated at approximately 19%. However, analyses of more recent data from the past decade suggest a materially lower success rate, closer to 10%.

Study	Probability of FDA Approval for Products Entering (%)				
	Preclinical	Phase I	Phase II	Phase III	FDA
Recombinant Capital (n.d.)	19	—	30	60	—
Hansen (1979)	—	19	50	—	—
Sheck, Cox, Davis et al (1984)	—	17	—	—	—
Grabowski (1991)	—	23	31	64	—
Bienz-Tadmor, DiCerbo, Lasagna (1992)	—	29	—	—	—
Wenzel (1993)	—	—	30	63	—
Struck (1994, biotech)	38	69	79	92	100
Struck (1994, conventional NCE)	11	25	33	66	100
DiMasi, Seibring, Lasagna (1994)	—	—	—	—	83
Kaitin (1995)	—	20	30	62	75
Grosse, DiMasi, Nelson (1996)	—	21	—	—	—
DiMasi, Hansen, Grabowski, Lasagna (1995, 1997)	—	23	31	64	—
Lehman Brothers (1997)	4	10	30	63	90
Myers, Howe (1997)	22	24	32	64	75
DiMasi, Manocchia (1997)	—	—	—	—	90
DiMasi (2001)	—	23	33	79	81
Gilbert et al (2003)	—	8	—	—	—
DiMasi et al (2003)	—	22	—	—	—
Adams and Brantner (2006)	—	24	—	—	—
Adams and Brantner (2010)	—	24	—	—	—
Paul et al (2010)	4	12	22	64	91
Mestre-Ferrandiz et al (2012)	—	11	—	—	—
Hay et al (2014)	—	10	16	50	83
Thomas et al (2016)	—	10	15	50	85
DiMasi, Grabowski, Hansen (2016)	—	12	—	—	—
Bio, Biomedtracker, Amplion (2016)	—	10	15	50	85
Takebe (2018)	6	19	26	51	88
Wong et al (2019)	—	14	35	59	83
Bio, PharmaIntelligence, QLS (2021)	—	8	15	52	91
Bloeme, Jansen, Krul, and Geutjes (2021)	2	5	11	44	92
Average	**13%**	**19%**	**30%**	**61%**	**87%**

4.2 Risk Weightings Adjustment

Risk-Adjusting Net Cash Flows

Future cash flows are adjusted using phase-specific probabilities of successful progression through the drug development process. These probabilities reflect the likelihood of advancing from one stage to the next and are applied to both projected revenues and remaining R&D expenditures.

Based on a meta-analysis of 30 published studies, the probability weightings summarised in the table below have been derived. For instance, a compound currently in the preclinical stage has an estimated 13% probability of ultimately reaching the market. Accordingly, projected sales-related cash flows would be multiplied by 13%. Similarly, R&D costs associated with subsequent stages (e.g., Phase I) should also be probability-weighted—Phase I costs, in this case, by approximately 71%.

The highlighted probabilities in the table indicate the likelihood of progressing from the current phase to the next. Cumulative success probabilities naturally increase as the candidate advances through development.

It is important to note that phase transition probabilities vary by therapeutic area—for example, cumulative success rates average around 5.3% for oncology, 7.5% for respiratory, and 9.3% for non-oncology programs [1].

Current Phase	Future Phase: Preclinical	Phase I	Phase II	Phase III	FDA	Market
Preclinical	100%	71%	45%	22%	15%	13%
Phase I		100%	64%	31%	22%	19%
Phase II			100%	49%	34%	30%
Phase III				100%	70%	61%
FDA					100%	87%
Market						100%

Source: [1] Bio, PharmaIntelligence, QLS – Clinical Development Success Rates and Contributing Factors 2011-2020 (2021)

4.3 Discount Rate

Discounting Risk-Adjusted Cash Flows
To determine the present value of drug assets, future risk-adjusted cash flows are discounted by an appropriate annual discount rate. This rate represents the time value of money and the general business risks inherent in biotechnology ventures, including management, financing, manufacturing, and intellectual property risks. Importantly, product development risk is excluded from the discount rate itself, as it is already incorporated through the phase-specific probability adjustments applied to the cash flows.

In his *AusBiotech* presentation, *"Biotech Product and Company Valuation –Fundraising and Licensing"* (June 2020), Patrik Frei highlighted that the applicable discount rate varies according to the company's stage of maturity [1]:

Early Stage	Mid Stage	Late Stage
12-28%	10-22%	9-20%

Similarly, Frei et al. (2016) emphasised that the discount rate captures general business risk and the cost of capital when calculating the present value of expected, risk-adjusted cash flows. Typical discount rates in the life sciences sector range between **10%** and **26%**, depending on company size and funding structure [2]. Large pharmaceutical companies generally apply lower discount rates due to their diversified portfolios and stronger balance sheets, resulting in higher project valuations. In contrast, early-stage biotechnology firms and private investors often
adopt higher discount rates, reflecting higher capital costs and elevated business risk.

The discount rate is commonly derived using the Capital Asset Pricing Model (CAPM) framework, comprising:

- **Risk-Free Rate:** Typically proxied by long-term government bond yields;
- **Market Risk Premium:** Generally assumed at ~6%, representing the expected excess return of the overall market relative to the risk-free rate; and
- **Beta (β):** A measure of the covariance between returns of the biotech company and the broader equity market, capturing sector-specific volatility and sensitivity to market movements.

Sources:
[1] Patrik Frei – Biotech product and company valuation – Fundraising and licensing (2020)
[2] Frei, P., & Peire, A. (2016). What is the value of a deal? Nature Biopharma Dealmakers, B27–B28.

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