Biotechnology
Funding, Risk & Valuation

Biotechyst
BIOTECHNOLOGY INSIGHTS

Development phase, Risk & Funding

Raising funding:

- Critical, especially in the early pre-revenue research and development stages including for clinical trials and the regulatory approval lifecycle - see development phase table alongside
- Often occurs in stages to meet milestones in the development and regulatory approval processes
- Affected by factors including:
  - Internal entity considerations
    - Board & management
    - IP assets
  - External factors
    - Regulatory & political environment
    - Competitors
    - Economy, stock markets & exchange rates

Risk

- Highest in the research and development stages (including trials), particularly during phase 2 trials - success of the product in clinical trials, raising sufficient funding, regulations and FDA approval
- Affected by product pipeline - more products could signal less risk/more diversification (depending on stage of development)
- Risk inversely related to cash balance; directly related to funding requirements - below right

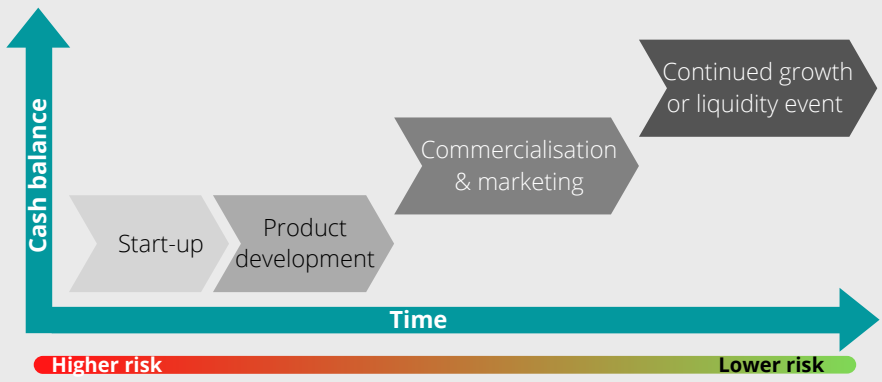
Funding types:

- The type of funding secured in the early stages of a venture affects the capital and ownership structure of the entity:
  - Dilutive - diminishes ownership
    - Equity for capital – angle investors or venture capitalists
    - Share issue to new investors through public or private funding round
  - Non-dilutive
    - R&D tax incentives
    - Foundations (NGOs, NPOs)
    - Industry partnerships
    - Debt
    - Revenue

Development phase features and risk

Development phase	Characteristics	Activities	Risk & Investor considerations
Start-up	• Often based on one promising innovation (technology or platform)	• Prototyping • Entity establishment – legal structures, registration, governance structures • IP asset establishment or acquisition i.e. universities	• Risk: High • High level of failure • Funding sources: friends/family, seed & angel investors, government grants
Research & Development	• Product development • Clinical and field trials	• Proof of concept testing & expansion • Toxicology studies (*in silico*, *in vitro*, animal) • Clinical trial start • Regulatory requirement focus • IP management and strategy • Commercial considerations • Seek funding (for next phase)	• Risk: Highest • More data available on potential success of the product • Distinguish between early & late stage clinical trials – successful phase 2 clinical trials critical • Funding sources: angel investors, government grants, venture financing, private equity, partnerships, IPO
Commercial-isation & Marketing	• Revenue generation • Internal exploitation of IP assets – take to market • Out licensing or sale of IP assets and/or technology	• Cash flow – up-front milestone or royalty payments, revenue (dependent on regulatory approval) • Reimbursement • Approval by other regulatory bodies for international expansion	• Risk: Variable - depends on market uptake and product success • Funding: strategic partners, capital markets
Continued growth or liquidity event	• Post-launch support and strategic exploitation of IP asset (life of patent portfolio)	• Use of revenue for accelerated growth and development or in-licensing of new technologies • Spin-out or subsidiary company creation for further specialisation in a new technology(ies)	• Risk: Lower – several assets and/or revenue stream offer diversification

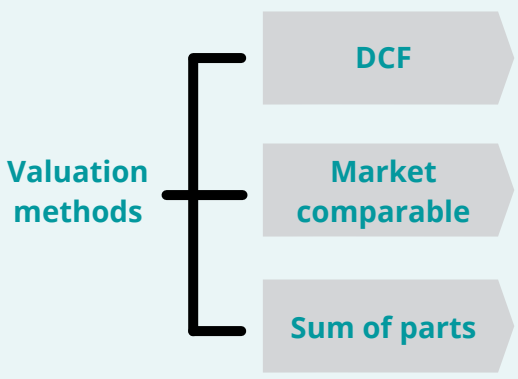
Cash balance and risk over time



AusBiotech. Guide to Life Sciences Investing. https://www.ausbiotech.org/documents/item/451 (2018).

Valuation methods

Biotechs are challenging to value given their unique lifecycle and the nature of their assets, i.e. largely IP/non-tangible assets - valuation of which is specialised and complex



Valuation methods used differ to most other sectors, and include:

- Discounted Cash Flow (DCF) – based on future positive and negative free cash flow projections
- Market comparable – multiples for calculating value based on data from public, peer-group companies; market capitalisation, peer/comparable enterprise values (disease area, stage of development, size (employees)
- Sum of parts – total net present value (NPV) of a company; sum of risk-adjusted NPV (rNPV) of lead product(s) in development and the DCF of all other company operations, takes probability of success/failure into account; rNPV calculation can be split into:
  - Development Phase - cost and timeline for bringing product to different markets
  - Market Phase – disease prevalence (market size), cure vs prolonged treatment, drug pricing in different markets, competition, development timelines for different markets
  - Risk Adjustment – product-specific attrition risk
  - Discounting to Present Value – general business risk and cost of capital

Industry nuances summary

- Often unprofitable with no or limited revenue
- High risk - high chance of failure i.e. up to ~90% of drugs in development either do not reach the approval stage or are not approved / 5–15% success rate on commercialisation attempts
- Long product development lead times i.e. successful companies often take ~10 to 15 years to achieve commercialisation
- Potential for high reward:
  - For drugs/products which do get approved
  - For early/start-up stage investors if the company is acquired or licensed by a larger entity
- Limited dividends due to limited revenue generation
- DCF models often used to value early-stage biotechnology companies, however success is linked to whether products reach approval and are approved

References and further details

- AusBiotech. Guide to Life Sciences Investing. https://www.ausbiotech.org/documents/item/451 (2018).