



Operating Strategy

(or how to be a CEO)

Khoa Cao



Agenda

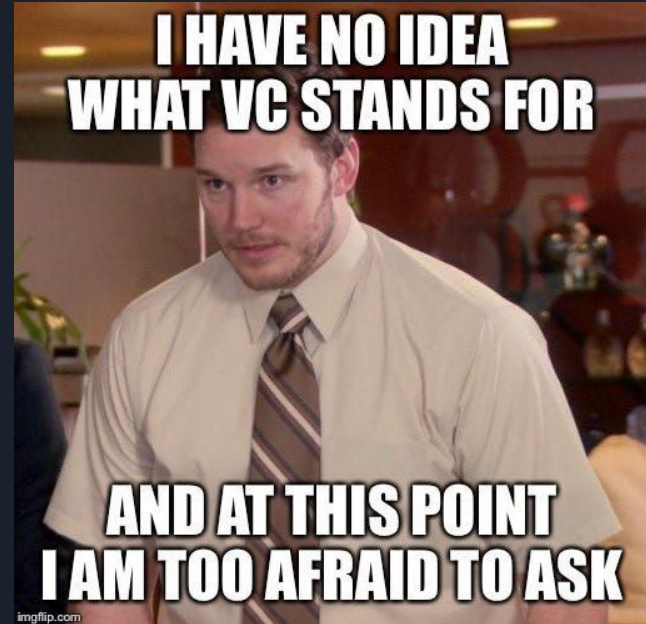
Operating Plan

Exit Strategy

Hiring/Staffing

Boards

Investors and VCs





Why learn about this at all?

CEO has three jobs that can't be delegated - 1) operating strategy, 2) hiring and 3) VC funding.

Good operating plan brings together everything about your strategy (clinical, regulatory, reimbursement, R&D, IP, commercial).

Bad operating plan = waste of time/money, no VC funding



Operating Plan

- High-level development plan (up to market launch)
- Detailed operating plan for next 1-2 years
- Budget
- Market model (pricing and peak revenue estimate)
- Cost of goods sold (COGS) and gross margin estimate

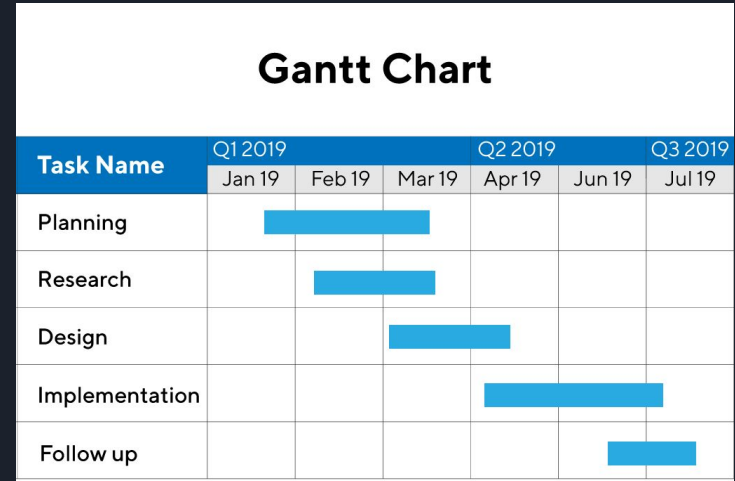
High-Level Development Plan

Gantt chart

Capture key activities and milestones to launch

Steps: Identify key activities and their sequence/timing. Capture key cost elements.

Categories: Product Dev/IP, Reg/Trials, Commercial, Reimbursement





Milestones

Startups are primarily about value creation through risk mitigation.

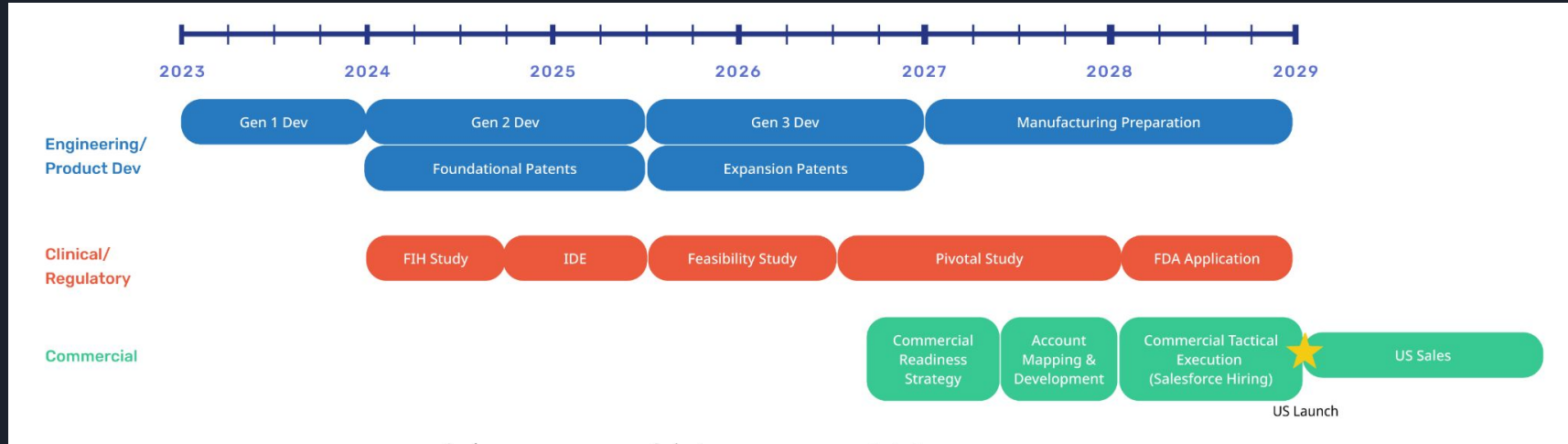
Funding (Seed, Series A, etc.) should be timed with key milestones.

Milestone = Key Risk Mitigated

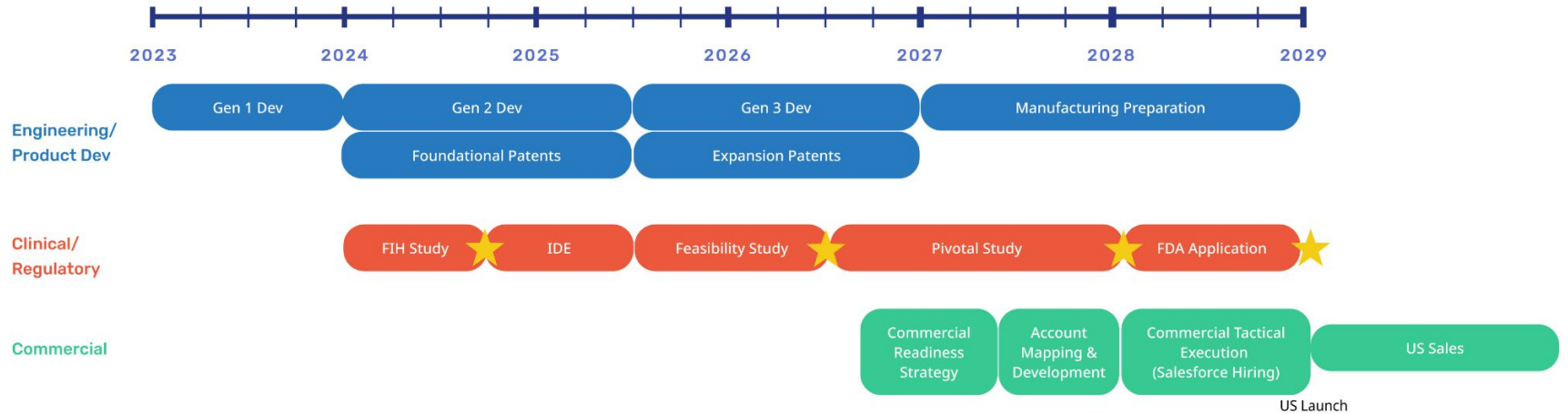
For medtech, milestones are almost always completion of clinical trials.

However, a good CEO will ensure that engineering, IP, commercial risks are mitigated together in the same milestone.

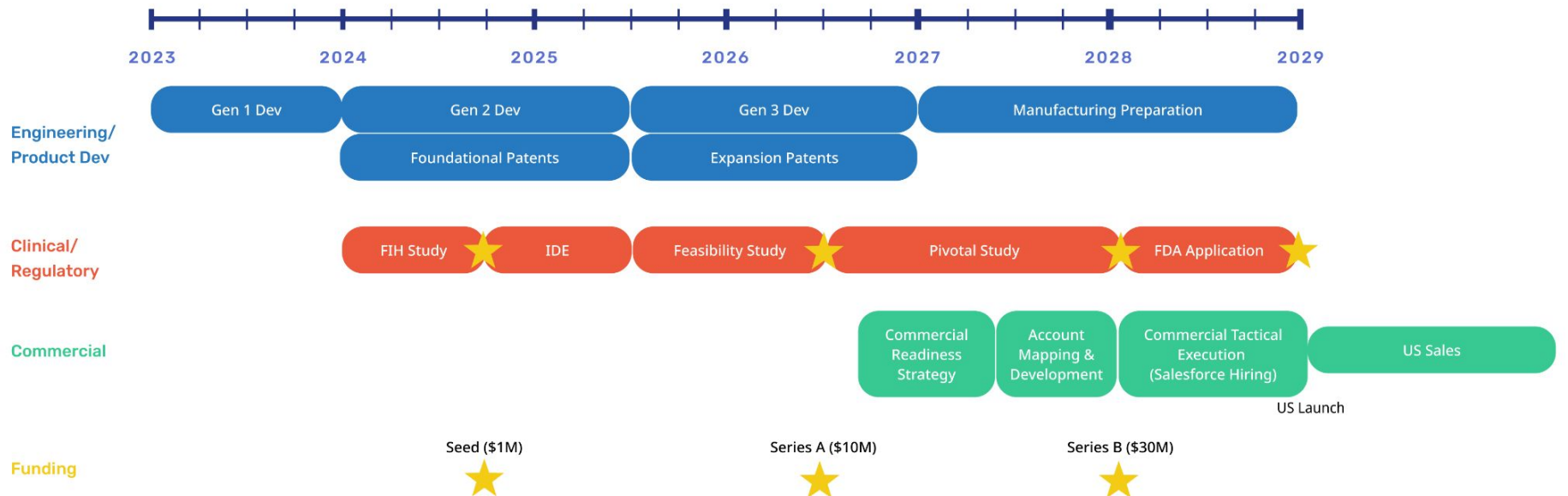
High-Level Development Plan



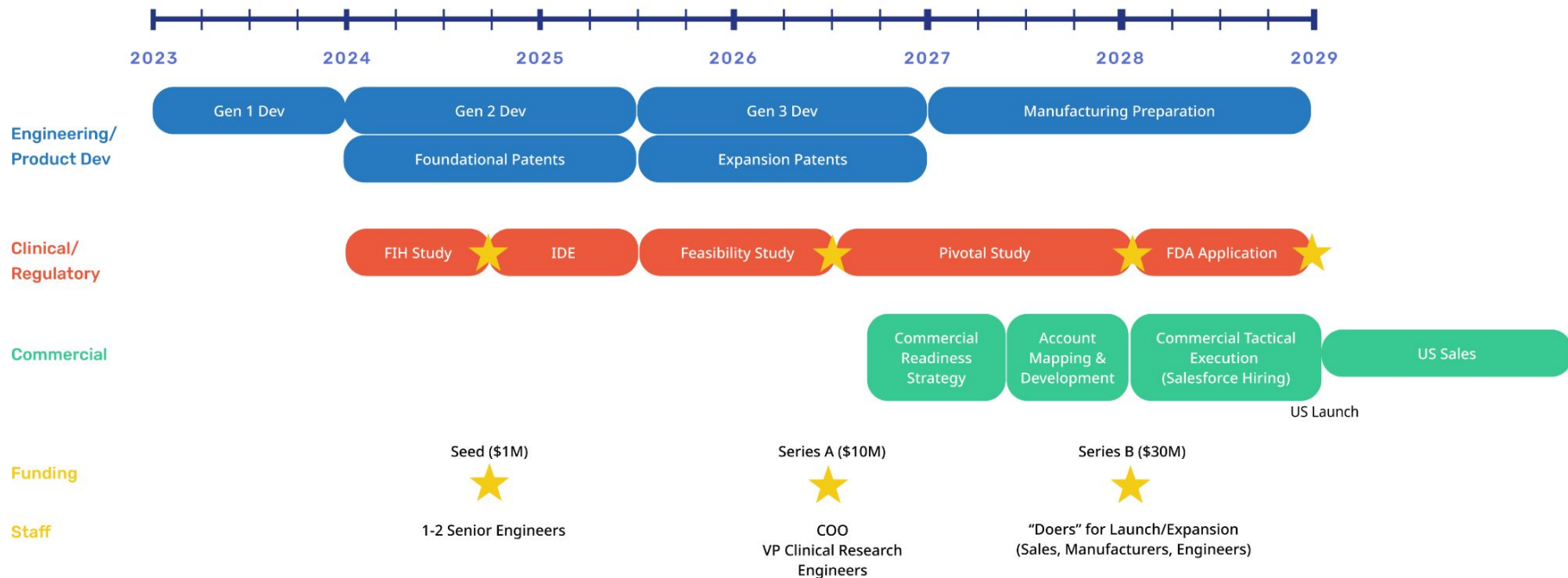
High-Level Development Plan



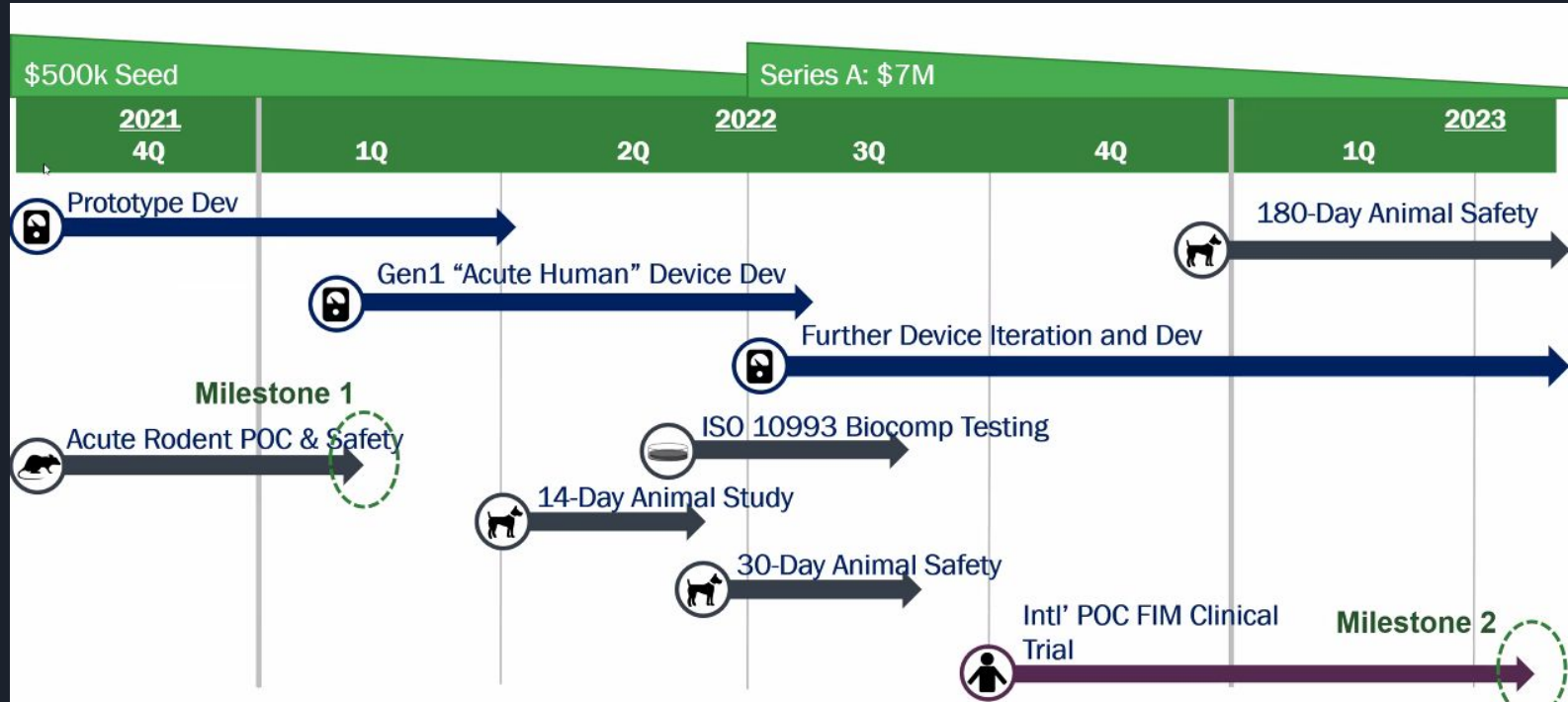
High-Level Development Plan



High-Level Development Plan



Near-Term Development Plan





Group Activity

Prepare a long-term operating plan for your company.



Budget

Iterative process with development plan (e.g. our plan requires too much money -> maybe we should be less aggressive on milestones)

Categories: Staffing/Consultants, Clinical Trials, R&D/Engineering, Office Hire/Supplies, Marketing, Employee-Related Expenses (e.g. Activities, Conference Travel), etc.

Ask for 30-100% more from VCs (“strategic cash”)



		2021		2022		2023		2024		2025		2026											
		Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4				
		Sep-21	Dec-21	Mar-22	Jun-22	Sep-22	Dec-22	Mar-23	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24	Dec-24	Mar-25	Jun-25	Sep-25	Dec-25	Mar-26	Jun-26	Sep-26	Dec-26
Employee Related Expenses	Company Activities	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Education and Training	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Books, Publications, Subscriptions	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Membership Dues	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Registration/Conference Fees	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Meetings	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
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Travel and Entertainment	Transportation	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Lodging	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Employee Meals	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Mobile and Entertainment	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Other T&E	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
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Marketing Activities	Market Research	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Marketing Outside Services	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Meetings and Shows	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Promotional Materials	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Total Marketing	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Outside Services	Legal-Corporate	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Legal-Patent	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Consulting	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Clinical Consulting	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Reg Consulting	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Quality Consulting	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Engineering Consulting	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Accounting and Audit Fees	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
Total Outside Services	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
Supplies	Office Supplies	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Computer Supplies	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Furniture	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Equipment	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Software	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Equipment Rental	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	Tools	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	R&D Materials and Supplies	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
-Custom components	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
-Made-to-spec. Tools & Molding	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
-Other Manufacturing Expenses	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
Total Supplies	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -



Market Assessment

Determine potential financial value of the opportunity.

Important to be honest - investors know when you're making it up.

Depends on the target population and whether you have selected the right level of abstraction.

Consider market forces (e.g. growth, contraction, payer/provider incentives).

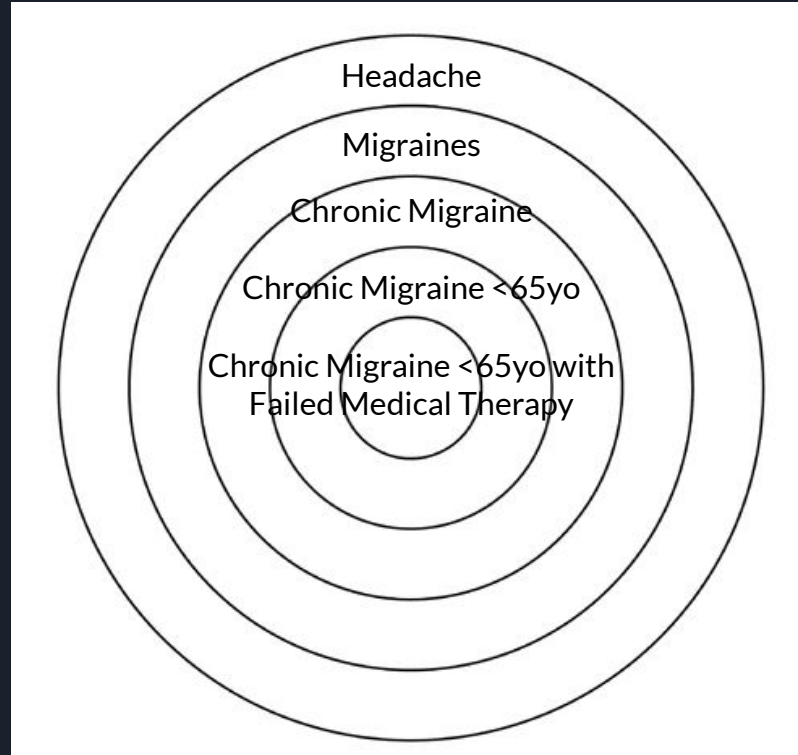
Target Populations

Too broad = unlikely your device solves for everyone

Too narrow = no market

Best is usually reasonably narrow with expansion opportunity

First-time founders usually err too broad = looks naive to VCs



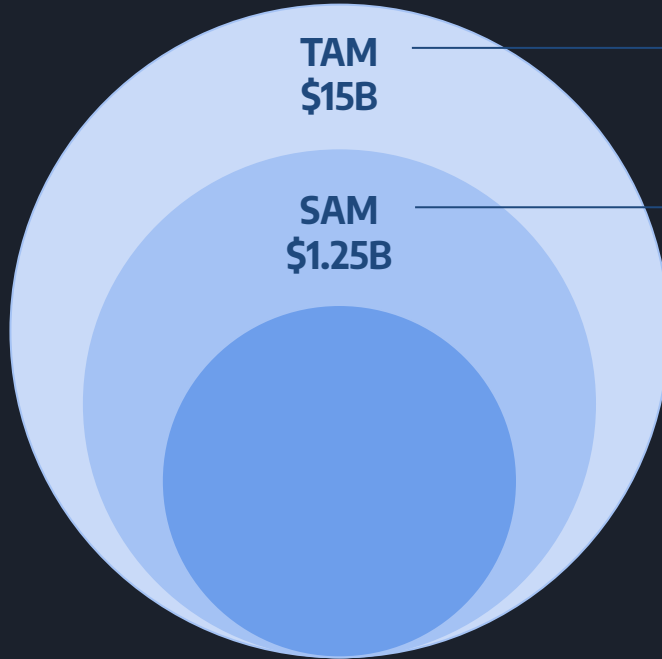


Top-Down Market Assessment (TAM/SAM)

1. Figure out the “customer unit” (e.g. procedures, tests, annual fees, sale of capital equipment).
2. Determine the total number of eligible customer units per year. Sources include literature, public databases, competitors.
3. Determine your average selling price.
4. Multiply units x price globally for TAM and locally for SAM.



Market Assessment



$\$15B = \$500 \times 30M$
30M chronic migraine <65y globally

$\$1.25B = \$500 \times 2.5M$
2.5M chronic migraine <65y in US

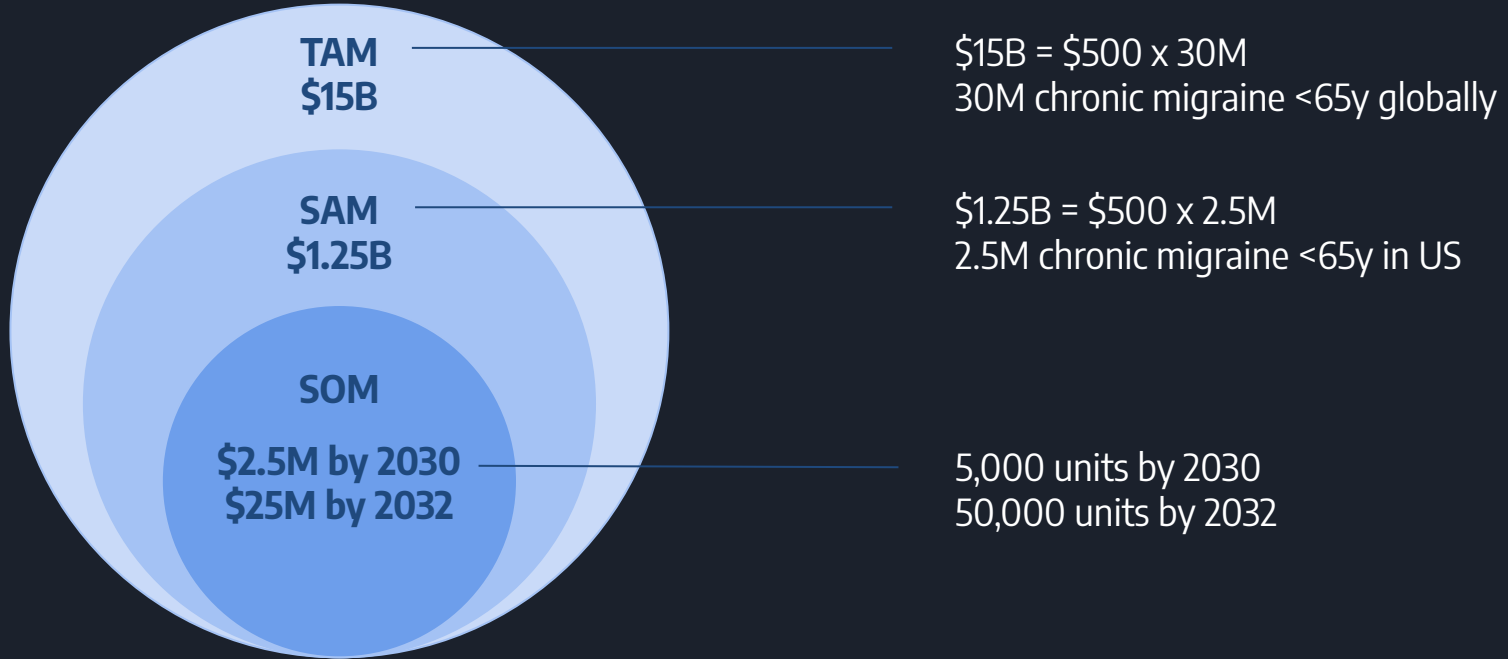


Bottom-Up Market Assessment (SOM)

1. Figure out how many units you can realistically sell in years 1-3 post-launch.
2. Depends on the device, but will likely be restricted by sales cycle (capital equipment), sales staff (usually 3-6 staff members), or production capacity.
3. Multiply units x price for SOM.

Again, be realistic. 15%+ market penetration in the first year isn't realistic.

Market Assessment





Group Activity

Revisit your team's market assessment.

Assess whether you have selected the right population abstraction.



COGS and Gross Margin

COGS: Cost the product/service

- **Products:** Raw materials, direct/indirect labour, sterilisation/packaging, shipping/storage, any contract manufacturing overhead
- **Services:** Direct labour costs, critical infrastructure to deliver service

Gross Margin: (Selling Price - COGS)/Selling Price

- Bill-of-Materials ("BOM"): \$1,800 estimate
- Direct Labor: Not sure, depends on scale, expert opinion is ~\$300 for US labor
- Indirect Labor: +5%
- Packaging/Sterilization/shipping/etc: +10%
- Profit for Contract Manufacturer (if used): +30%
- Bottom-up total: ~\$3,045

$$\text{Gross Margin} = \frac{\$30,000 - \$3,000}{\$30,000}$$

High estimate:
90%



Gross Margins and Implications

75-80% is typically the lowest acceptable gross margin for devices

(Slightly softer for larger devices, e.g. MRI)

90%+ gross margin is considered excellent/extremely desirable

Compare to gross margins in similar companies (all publicly traded companies report this in their SEC report).



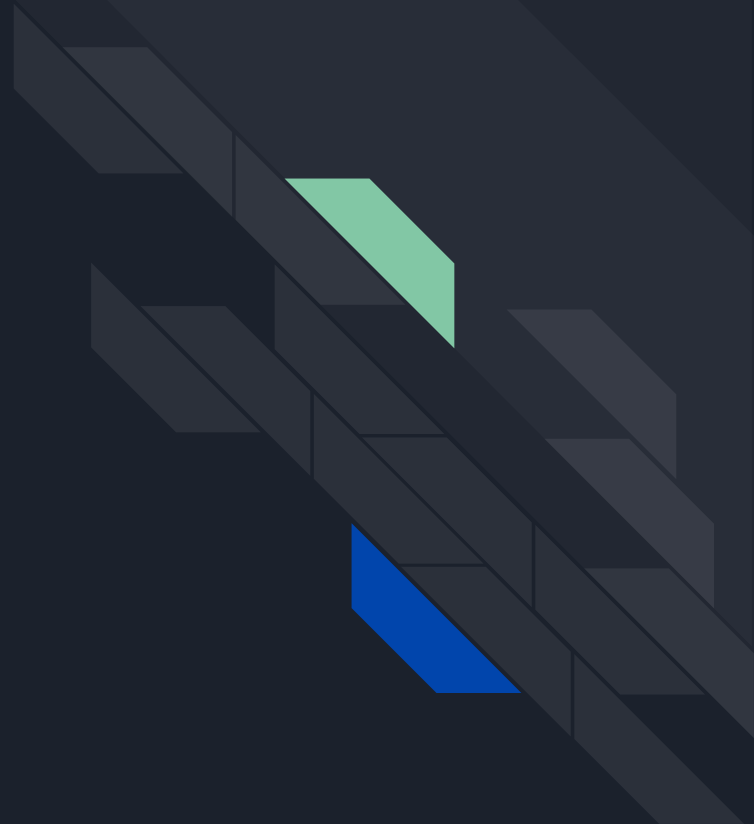
Market Advice

Be realistic. VCs are trained to spot inflated figures. It's also not worth wasting your time in an opportunity that will end up nowhere.

Attractive medtech opportunities have a gross margin of 80%+, >\$1B SOM and a \$50-100M annual recurring revenue within ~7 years.

These companies are attractive because they have many exit opportunities (IPO or acquisition are both very possible).

Questions?



Exit Strategy

Critical to plan your exit strategy from beginning

- **Acquisition:** 15-20 companies with buying power. You need to fit in the strategic plan and device portfolio of these companies.
- **IPO:** >\$1B SOM, >\$100M in ARR in 7-8 years, expansion potential

Alternatives are available, but you need to know from the start (e.g. acquihires, licensing, non-for-profit) because strategy is very different.





Acquisition

Requirements: Strong IP, >\$50-100M in ARR, 80%+ gross margins, +20% growth p.a.

- SOM <\$600-800M -> \$50-150M acquisition
- SOM \$1-3B -> \$700-900M acquisition
- SOM >\$3B -> \$1B+

Never deal with “business development” teams. Acquisitions should occur through investors and advisors who have connections to the CEO/executive team.



IPOs

Company on the public market. Not as common for medical device companies.

Cost of IPO and public reporting is significant (\$100M)

Will fit companies with blockbuster product and significant expansion potential

Requirements: Strong IP portfolio, >\$50-100M in ARR, 80%+ gross margins, +20% growth p.a., significant expansion potential



Group Activity

Figure out what your exit strategy is.

If acquisition:

- Potential acquirers
- Portfolio
- Previous acquisition activity

If IPO:

- Prior companies which have IPO'ed in the space
- Market capitalisation
- Whether stock went up or down after IPO



A note on hiring.

Seed = CEO, CTO and many consultants

Series A = CEO, CTO, Engineering Team and many consultants, maybe fractional CFO

Series B = CEO, CTO/VP of Eng, VP Clinical/Reg, maybe COO

Wrong person in first 10 people = company death (avg. company has 10-12)

First-time founders OK as long as rest are experienced veterans

A note on equity.



Funding round = 10-30% equity

1 year cliff with 4-6 year vesting.

Pre-Seed: Consider an equal split between founders. Companies require 7-10 years of effort, so “coming up with the idea” isn’t worth much. Founding advisors receive 5-10%.

Seed Stage: Executives receive 10-20%. Founding employees 1-5%. Advisors/board members 0.5-3%.

Series A Stage: The remaining employees for the life of the company share in a pool of 15-20% (“employee pool”). This will be a contractual requirement from VCs.



A note on advisors/consultants.

Experienced = prior exit or KOL

Get consultants for regulatory, reimbursement and IP

Pre-Seed: Strict rule against paying any consultants or advisors. If they ask, politely find someone else.

Seed: Paying is slightly OK, but only when absolutely necessary. Where possible, do all the legwork yourself. Avoid equity to any advisors unless absolutely necessary.



A note on boards.

The primary purpose of a board is to fire the CEO if they are underperforming.

Delay having a board for as long as possible. If you want advisors, get advisors.

VCs should not ask for a board at seed stage. If they do, find another VC.

Boards are mandatory at Series A. Members should be successful startup founders.

Investors

- **Institutional Investors (“VCs”)**: Professional investors, operate on 10-year cycles with 3-4x returns expected
- **Angel Investors**: Invest their own money, less time pressure, mission-oriented, smaller rounds (<\$1M)
- **Family Funds**: In-between Institutional and Angel Investors

VCs want **home runs** (10x) within ~8 years. If it will take you 8+ years to get to \$100M in ARR, VCs = nervous



logan bartlett
@loganbartlett

VC: we only invest in businesses with defensible moats and competitive advantages.

Founder: and what differentiates you?

VC: mostly our brand.



VC Assessment

1. **Team:** Founder-market fit, prior startup experience, effectiveness in execution, natural born leader, storytelling ability, best team, ability to walk through walls
2. **Product:** Idea maze to developing the product, understands that product will change when enters market so doesn't look at this
3. **Market:** Ultimate size of market is the only thing that matters. Mediocre teams can survive in great markets, but great teams will die on mediocre markets.



VC Advice

Warm Intro: Speaks to your tenacity and intelligence

Most failed pitches are because the right VC wasn't selected (e.g. thesis, competitor)

Budget 6-12 months for the first round. VCs expect to see a round every 18-30 months thereafter.

No one is going to sign an NDA. Focus on the problem rather than the solution.

Do not seek funding unless you absolutely need.

Pitching to VCs

Pitches should cover the following:

- Problem/Unmet Need
- Solution + Scientific Evidence
- Competitive Landscape
- Market, Business Model, Price
- Intellectual Property
- Operating Plan
- Regulatory and Reimbursement Strategy
- Team

Reading off slides = dead. If you can't answer a question = dead.

Best CEOs have “strong opinions, weakly held”.





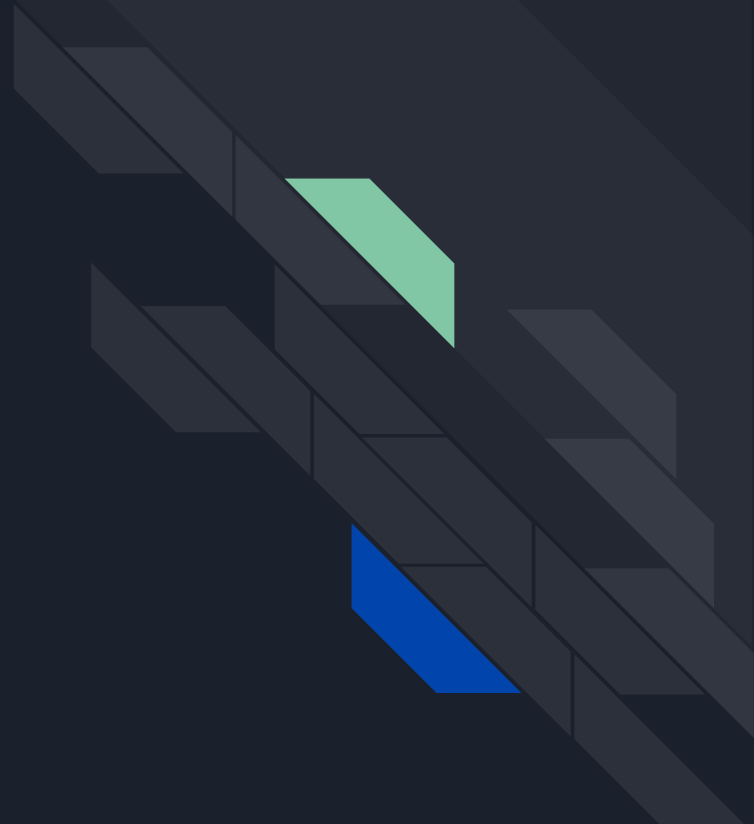
Research Funding

Sometimes used as additional money or initial funding

(+) non-dilutive

(-) ultra-long, competitor destroys you, eventually need VC funding anyway

Questions?





VC Instruments

A startup lawyer is required because terms can be extremely complicated.

Instruments are divided into economics (money/valuation) and governance (company control). Many founders are lured by a high valuation, but at significant loss of company control.

At pre-seed/seed, use a SAFE. SAFEs are fast and cheap (avoids company valuation, due diligence).

- SAFEs refer to convertible debt. \$500K is technically debt, until you do a series A, in which this converts to company equity at a predetermined rate.
- Uncapped SAFEs: Converts at same rate as Series A, extremely rare.
- Capped SAFEs: If cap is at \$5M, a series A raise below \$5M converts at the same rate. A series A raise above \$5M assumes a \$5M valuation for conversion.



Company Valuation

There are multiple techniques to value a company. However, most are appropriate for mature companies:

- **Comparable Company Analysis:** Find publicly traded companies that look/feel like startup. Determine their revenue multiplier and apply to startup (e.g. \$100M valuation for \$20M ARR = 5x multiplier).
- **Discounted Cash Flow Analysis:** Value of company is equal to present value of future cash flows with discounting.



Company Valuation

Answer: “What Do I Need to Believe?” Analysis

- If we provide \$10M for \$20% of the company, the company is worth \$50M.
- We need \$100M return for a home run (10x), which means the company is worth \$500M.
- Currently, public companies are worth 5x their revenue for this field.
- This means the company needs to attain \$100M ARR in the next 5-10 years.
- Is this possible? If not, decrease the valuation. If definitely yes, increase the valuation.