

Concept-to-Company: An Investigator's Guide to Starting a Business January 25, 2023

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AGENDA

- When & How to Form a Company
- Capital Sources
- Key Features of Investible Companies
- Important Considerations in Developing a Pitch Deck
 - Non-Disclosure Agreements
 - Key Points to Consider
- The Pitch Deck

WHEN & HOW TO FORM A COMPANY



STAGES OF A COMPANY

EARLY STAGE

- Idea stage concept
- Proof-of-Concept reduced to bench model; drawing, prototype
- Seed minimum viable product released to establish a scalable, repeatable, profitable business model
- Start-up or Launch commercial product released

LATER STAGE

- Growth company past start-up hurdles, beginning to grow rapidly
- Maturity



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STEP One – Intellectual Property (IP)

PATENTS, TRADEMARK, COPYWRITE, TRADE SECRETS

- US, xUS, worldwide existing vs planned
- Issued vs application dates of issuance, application, office action
- Freedom-to-Operate (FTO) informal vs formal

DOES IP EXIST?

- If none hire patent attorney & start the process <u>before</u> public disclosure of technology (e.g. publication in scientific journals)
 - Know rules around US & XUS patent requirements relative to publication/disclosure date

WHO OWNS IP?

- If university disclose to Tech Transfer Office (TTO)
 - Prepare to negotiate licensing terms with TTO
- If other entity need for negotiation to acquire rights to IP
- Your company will need to own/license IP rights seek legal advice



STEP Two – Company Formation

COMPANY STRUCTURE

- C-Corp, S-Corp, LLC, Sole Proprietorship
- Investors will insist on C-Corp
- Incorporate in business-friendly states Delaware is preferred

REQUIREMENTS FOR A C-CORP

- Chief Executive Officer
 - > Part-time initially is ok but be prepared for full-time commitment
 - Prior relevant experience is preferred
- Board of Directors
 - > Odd number of Directors start with 3, 5 is better
 - > Should be outsider controlled (not paid by company)
 - Directors should bring real value/experience



STEP Two – Company Formation

STOCK & STOCK OPTIONS

- First Board action authorize stock & set valuation
- Authorize incentive stock option plan
 - Employees
 - Board members
 - Advisors
- DIRECTORS & OFFICERS INSURANCE
 - Required for most outside directors
- RETAIN CORPORATE LEGAL COUNSEL



STEP Three – Licensing Agreement

OBTAIN RIGHTS TO IP

- Retain legal counsel representing the company
- Negotiate licensing terms friendly to company
 - Investors want their money to support the company not the university or holder of IP
 - > Low up-front & milestone cash payments
 - Single digit royalty on early product revenue
 - Back loaded terms
- World-wide rights preferred
- Multiple indications if possible
- Right to sublicense

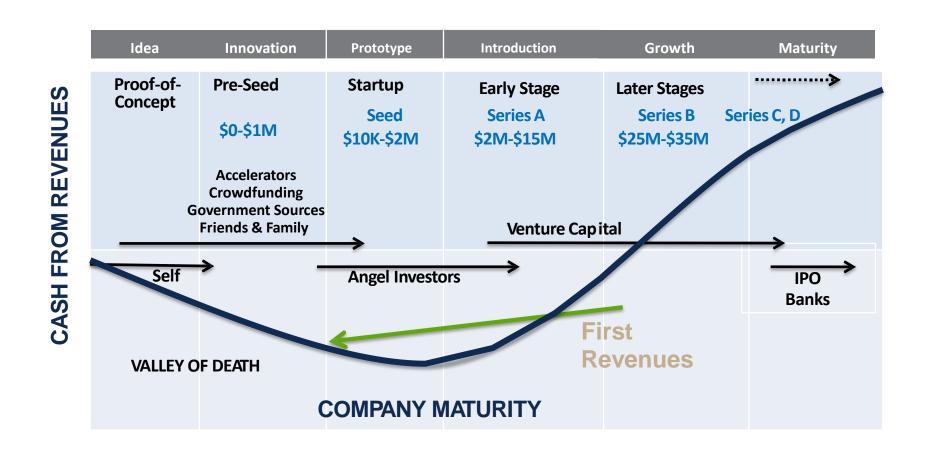


STEP Four – Funding

EARLY-STAGE SOURCES OF CAPITAL

- Founders
- Friends & Family
- Non-Dilutive Capital
 - Grants (e.g. NIH SBIR Phase I)
 - ➤ Nonprofit Sector-Specific Organizations grants (e.g. AHA, ADA)
 - Process is slow starter money
 - Provides validation of company & technology
 - Springboard for subsequent fund-raising activities

CAPITAL SOURCES OVER THE STARTUP LIFECYCLE





CAPITAL AMOUNTS INVESTED

Founder, Friends, Family

Angels

Venture Capital

(Crowdfunding)

Bank (Debt)

\$0-\$200K

\$50K-\$2M

\$1M & up

up to \$50M

Any Amount

ANGELS vs VENTURE CAPITAL

 Angels – high network individuals who invest their own capital (& usually their experience) with the intent to create value & help the local economy

 Venture Capital – investment funds, managed professionally with intent to create value greater than available through traditional investments

KEY FEATURES OF INVESTABLE COMPANIES



WHAT DO ANGELS LOOK FOR?

- Unique product or service that...
- Solves a problem (relieves a pain) that is...
- Worth solving (>\$100M market) and can be...
- Reached (distribution strategy) with a...
- (Experienced) team that can execute & is...
- Capital efficient with...
- Exit potential



WHAT DO ANGELS LOOK FOR?

- Balanced, skilled & experienced team
- Important problem
- Working solution
- Good value proposition
- Customer traction
- Sustainable competitive advantage
- Solid go-to-market strategy
- Adequate raise based on solid financial plan
- Exit strategy



FUNDABLE MANAGEMENT TEAMS

CEO

- Coachable (very important)
- Integrity
- Prior C-level experience, leadership
- Vertical experience
- Team members identified

Team

- Balanced & complete
- Experience working together

SIZE OF THE OPPORTUNITY

Scalable

- \$20M (minimum) in revenues in 5 years
- (VCs look for >\$100M)
- Large niche market
 - Achieve high revenues
 - With minimum competition
- High gross margins
 - Growth with internally generated cash
 - Requires less investment capital

PRODUCT & TECHNOLOGY

- Product available for customer validation
 - Prototype
 - Beta test stage
- Unique technology
 - Patents, trademarks
 - Trade secrets
 - IP protection underway
- Manufacturability in quantity validated

INTELLECTUAL PROPERTY

- Patents, trademarks, trade secrets
- Competitive advantage is a "must have"
 - Competition with resources cannot just reverse engineer & compete
 - But, IP does not bring great value to startups because they do not have resources to defend
- Intellectual property primary value at exit
 - Acquiring companies insist on IP
 - Great IP adds substantial value at exit

MARKETING & SALES

- Customer validation is available
 - Investors need to verify with customers
 - Essential to investment
- Marketing/branding issues addressed
- Reasonable sales channels defined
- Some partnerships established
- Competitive advantage identified
 - Small competitors, fractured marketplace



IMPORTANT CONSIDERATIONS IN DEVELOPING A PITCH DECK



NON-DISCLOSURE AGREEMENT (NDAs)

- Most angels & VCs will not sign NDAs
 - See too many deals
 - Integrity is key to continuing business
 - Not motivated to steal technology
- May sign NDA in certain circumstances
 - During due diligence, not earlier
 - Covering a very narrow set of issues
- Business Plans no proprietary information!

KEY POINTS TO CONSIDER

- 10 minutes/10 slides typical pitch (time important)
- PowerPoint wide format slide numbers
- Large font see from back of room
- Presenter is CEO
- Business (not science) presentation you are selling
- Make your claims no time to substantiate claims
- Goal is to get the next meeting
- Bullet points not full sentences
- Text reflects speaker's words
- Avoid public solicitation of funds
- No truly confidential information
- Practice, practice use a timer



THE PITCH DECK

TITLE SLIDE

NewCo, Inc. Short tagline relaying what the company does

Presenter's Name
Title in the Company
Contact Information



PROBLEM

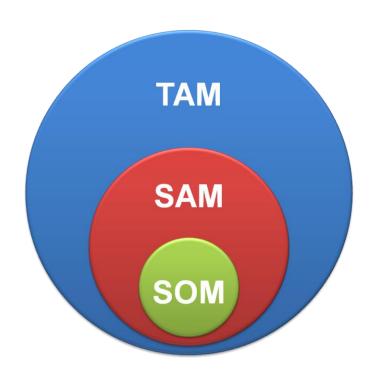
- Explain the problem/unmet clinical need
- What is the current standard of care/protocol?
- Highlight inefficiencies, gaps or suboptimal outcomes, process, safety or market access your technology will overcome



YOUR SOLUTION

- How does your technology solve the problem?
- Data: Use no more than 2-3 slides to explain
 - How your technology works
 - Any proof-of-concept data (in vitro, in vivo, preclinical or human) to support this assertion
 - No jargon terminology keep it simple
- For healthcare: reimbursement plan & healthcare economics
- Do not include any confidential information

THE MARKET OPPORTUNITY



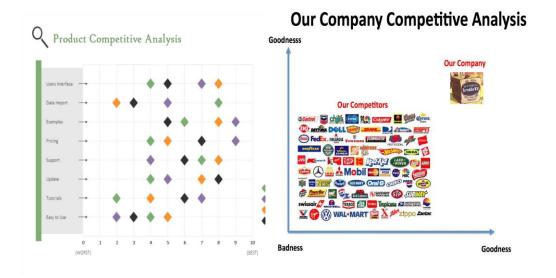
TAM/SAM/SOM

- Total Addressable Market = the entire world or wherever the technology can be used
- Serviceable Available Market = the market you will likely reach either geographically (eg. first world populations) or selected patients
- Serviceable Obtainable Market = the % of the SAM that you will likely capture (e.g. "10% of SAM")
- All values should be currency (not size of population); assumptions made to arrive at numbers should be presented or available in a backup slide, along with your financial model and other assumptions

COMPETITIVE LANDSCAPE

Ways to highlight your solution's or company's value proposition

	Trait 1	Trait 2	Trait 3	Trait 4	Trait 5	Trait 6
Competitor 1	~		~		V	V
Competitor 2		V	~			V
Competitor 3	~			~		
New Organization	~	~	~	~	V	V



- Focus on properties or characteristics that differentiate your product and/or company from the competition
- Competitive intelligence comes from many sources; keep track of references in notes where possible

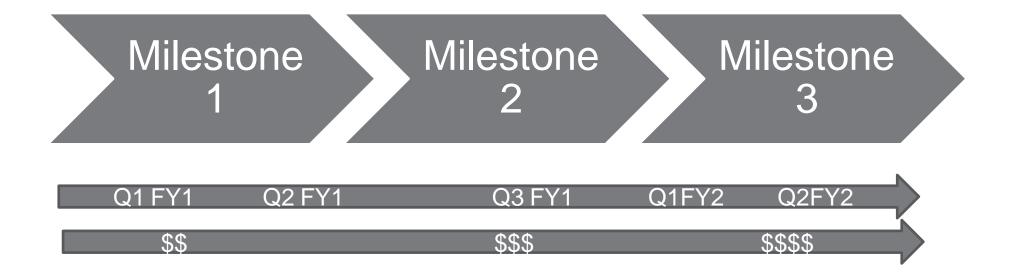


BARRIERS TO ENTRY

- This is primarily your IP strategy
- Present your IP portfolio
 - Patent applications & PCTs including numbers & dates
 - Patents granted & date
 - Country(ies) covered
- Differentiate composition-of-matter from method patents
- Provide only high-level summary of information on provisional patent applications
- Other potential barriers:
 - Specific know-how
 - Trade secrets or other secret sauce you own or have developed
 - Stated without details
- Freedom-to-operate (FTO) assessment informal or formal



PROJECT PLAN TO EXIT



- Major milestones in the development plan
- How much time & money (costs) will it take to execute plan
- How & when will you likely exit? (show recent comps, if any)
- Avoid a "public solicitation of funds" talk about costs, not fund-raising when audiences are NOT 100% accredited investors



TEAM

- Include key players from:
 - Management team
 - Founders
 - Advisors
 - Board of Directors
- Headshots, title & brief (1-2 sentences or few words) bio or description (e.g. ex-Pfizer or ex-Medtronic); include logos if possible
- Aggregate into 1 sentence (eg. "Combined 150 yrs experience in drug development from top 10 biotechs including Amgen, Celgene & Genetech with over 2 dozen products on the market")

SUMMARY

(projected during Q&A so gets the most air-time)

Bullet list of major points made during the pitch



-
-
- Last bullet is your "ask"

Company Name

Presenter Name

Title/Position in Company

Contact Information





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