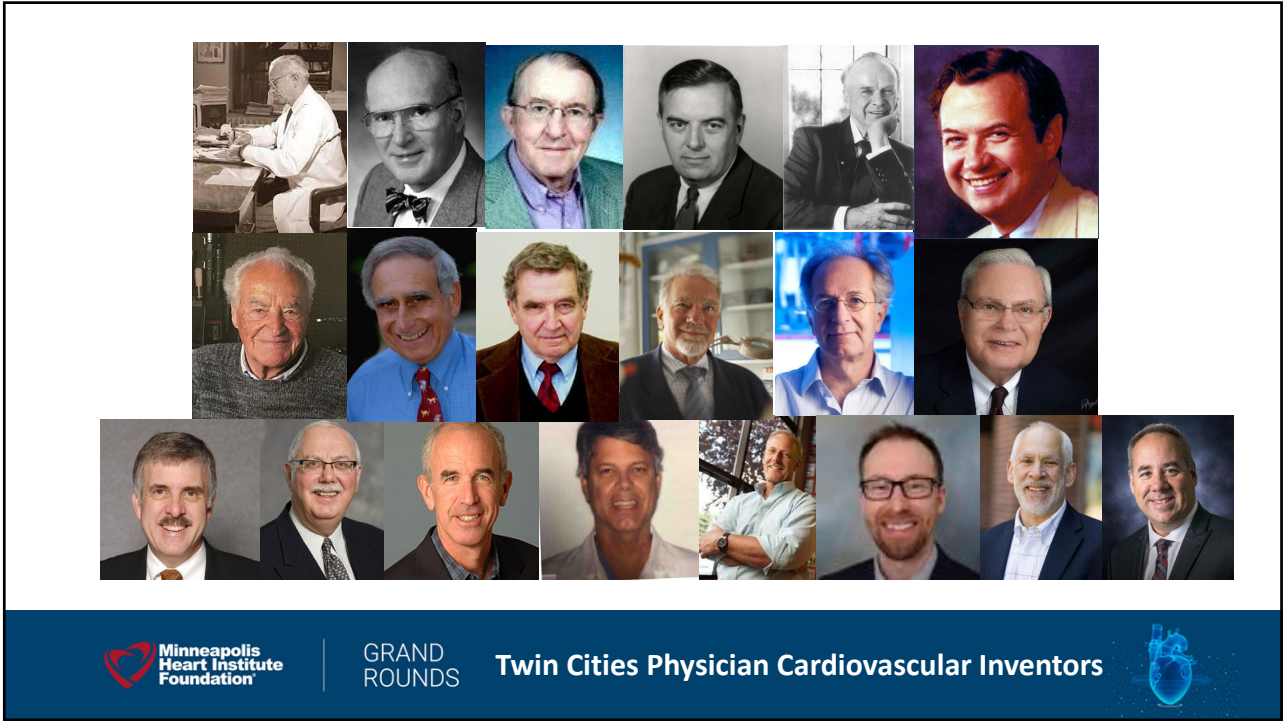




1



2

Why Does Minnesota Have So Many Cardiovascular Medical Device Companies?

The base was started by Dr. Owen Wangenstein, Chairman of Surgery at the U, who started modern experimental surgical science

The industry started with his proteges in the CV Surgery program at the U

Medtronic (Bakken, Lillehei), St Jude (Villafana, Nicoloff),

Mayan Plastics (DeWall, Johnson, Lillehei)

Then it grew

3M, SciMed, Angiomedix, CPI, Microvena, AGA, a lot

Created a base of scientists, engineers, technicians, attorneys, Regulatory specialist, experimental labs



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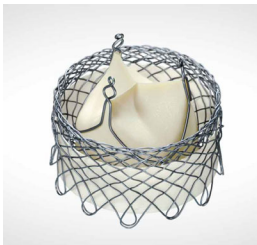
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ACIST Medical



1991-2001

HLT Medical



2001-2010

EGG Medical



2014-present



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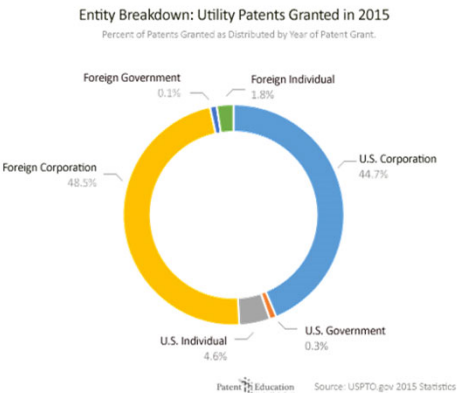
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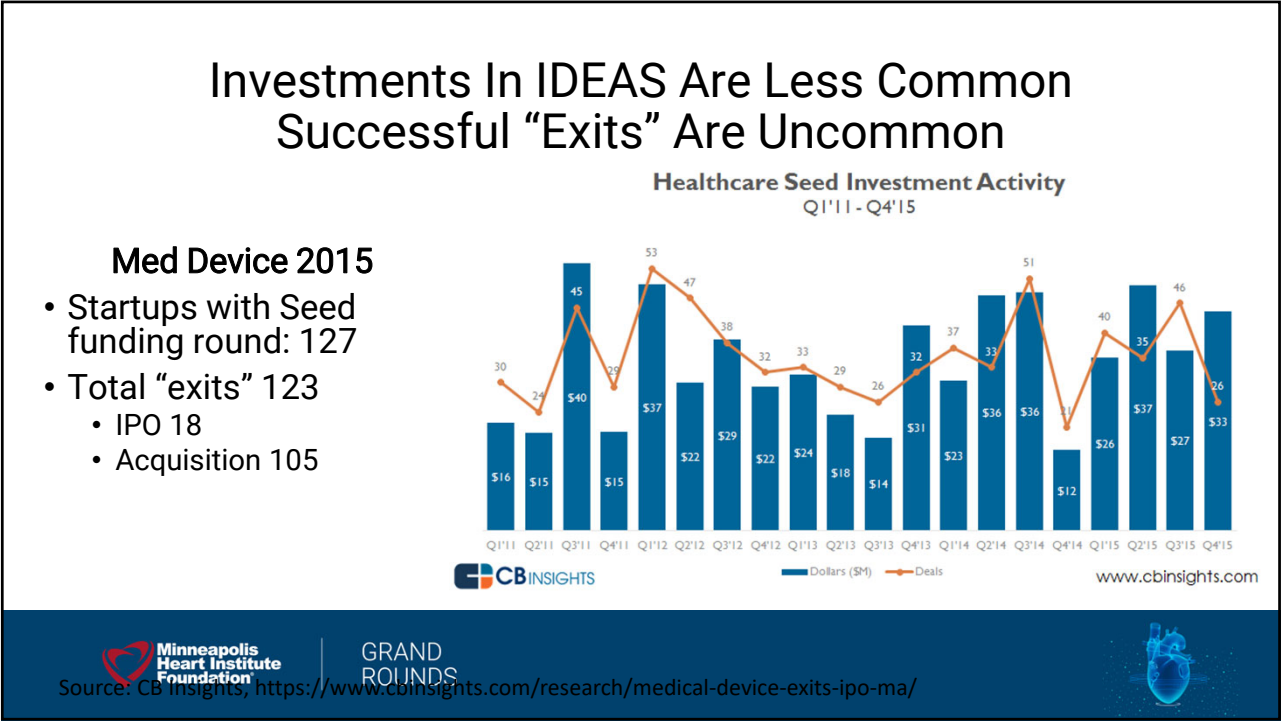
IDEAS Are Plentiful

- Total US Patent applications: 589,410
 - US origin 288,335
- Total US Patents granted: 298,408
 - US origin 140,969
- Total Med Dev patents: 17596
 - US origin 11636
 - MN 991 (#2)
 - CA 3189
 - Individual owned 1080



Source: USPTO, 2015

6



7



8

Non-Specific Screwing Around: Phase 1

- Define what “IT” is
 - What is patentable?
 - Has someone already done this?
- What is the market size?
- Does anyone want “IT”?
- What will it take to develop “IT”?
- Does this make economic sense?
 - Is this a company or a product?
- Figure out how to fund it- what valuation can you sell?

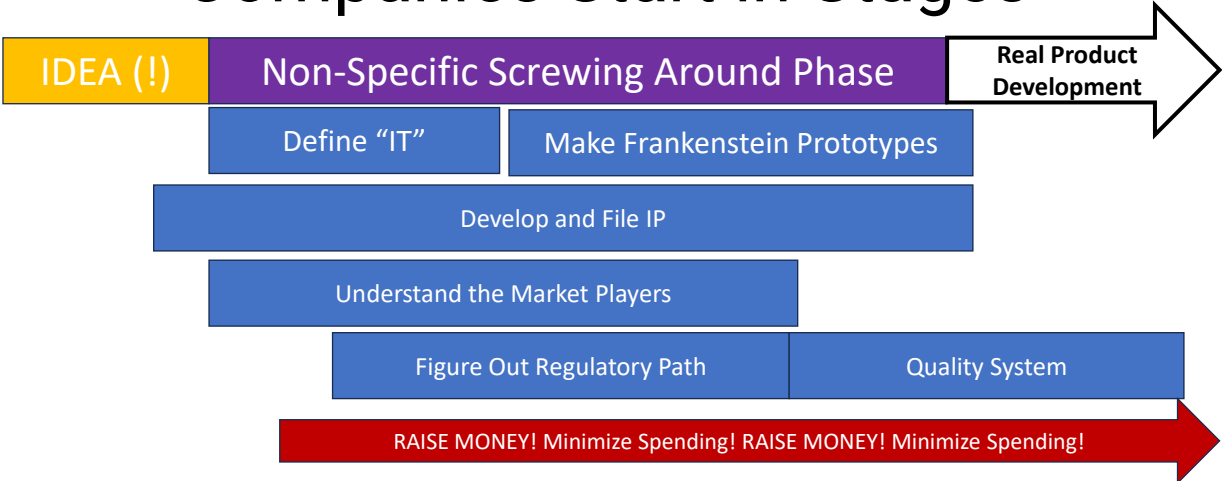


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9

Companies Start in Stages

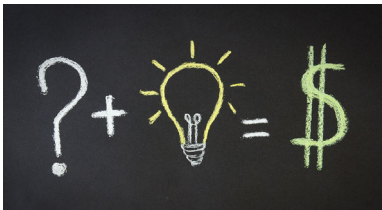


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10

“This piece of paper is worth a million dollars?”



An idea is valuable commercially only if:

- It can be protected
- The product can generate value (i.e., make an adequate return on investment)

An idea is not a company

*Most inventors think that the idea is 90%
It's really 1-5%*



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11

Patents

The three requirements for a patent:

- New
- Useful
- Not obvious

What is in the patent?

- Detailed description: Teach how it works
- Summary of prior work in the area
- Claims that you want to protect



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12

Patents Are Equity



- Classed as an asset
- Build a fence around the idea. Make the fence as expansive as possible
- Maybe file a defensive patent to stop a near-copy
- Patent problems come back to haunt-spend the money.

Because They Stop Copycat Competitors



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Before You File...

- You have unpleasant homework
 - **Search for existing patents**
 - www.USPTO.gov, Google patent
- Find the right patent attorney
 - Expect to pay about \$25,000 for the initial patent
- The first to file gets the patent
 - Early disclosure will make it public property
 - Be quiet and get non-disclosure agreements
 - Preserve your filing date with a provisional patent, if needed




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Simplified Medical Device Regulation	
FDA Device Class	FDA Pathway
Class 1- low risk Low risk- tongue depressor, needle, drape...	→ Self certify Notification
Class 2- moderate risk Monitor, catheter, syringe, gloves, injector, ventilator...	→ 510(k)- predicate device or de-novo Bench data, may require some clinical data 6-12 months review time
Class 3- high risk Implants, life-sustaining: heart valve, pacemaker, stimulators...	→ PMA Pivotal clinical study (2-4 years) 1-4 years review time



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15

How Big Is the Market?

Market size is a dominant factor in deciding if product development is worth the investment

The best ideas do the greatest good for the largest numbers

Great devices for very small numbers may not be feasible to develop

Market Size Potential

700 cases/lab
X 19,000 labs

X

2.8
catheters/case

=

37,361,500


37,361,500

X


\$20/catheter

=

\$747,230,000
/year



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To Be A Company, It Needs To Be A Big(ish) IDEA

- Market size should justify the expense of the company infrastructure (sales, HR, management, capital expense...)
- **The TOTAL market size** is important for fundraising
 - >\$1 billion market- great
 - 400MM to 1 billion- OK
 - <400MM- tough going
- **A single product is not a company unless it has a very large market potential**



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Licensing or Selling Your Idea

You are selling the patent rights and any early work you have done

- If you have no viable patent application, you will get little
- Value will depend on an analysis of the market size, investment needed, risk, uniqueness etc.- *do the homework to drive the deal*

How that deal is structured is important to you

- Up front payout (at least cover you costs so far)
- Royalty stream (% of gross, with minimums)



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Do You Really Want to Start a Company?



Starting a company is a learning marathon

- ✓ Legal work
- ✓ Learn to raise money
 - Starting with yours
- ✓ Team development
 - ✓ Starting with 1 (you)
- ✓ Find space
- ✓ Find people who design and build
- ✓ Develop a management team
- ✓ Learn regulatory
- ✓ Learn sales



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You Should Seek Out a Mentor



- Find people who have started businesses and can guide you
- An amazing number of talented people will help you
- Get an *experienced* med device attorney



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NSSA Phase 2- The Company

- Start a company
- Define the management team
- Recruit a Board
- Develop a regulatory strategy
- Raise money
- Build a prototype
- File more patents



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Types of Companies

- LLC (single or multiple partners)
 - Consists of Partner(s)
 - Initial losses flow equally to the partners, in proportion to the share they own
 - Can be difficult to add or subtract partners
- Corporation
 - S-Corp initially
 - Small corporation that issues shares (less than 100 owners)
 - Issues shares
 - **Tax deductible losses flow to the shareholders in proportion of their ownership**
 - Then become a C-Corp
 - The typical large corporation with many investors
 - Issues shares
 - **Losses do not flow to the investors' personal taxes**



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The Business Plan- a necessary evil



- You need a Business Plan (get help)
- The business plan is the blueprint for the business as you see it
 - Rational for the product and the market you are entering
 - The product line
 - **The plan for development, manufacture and marketing/sale**
 - **The management team**
 - **Equity projected structure (who owns what)**
 - **Risks**
 - **Competition**
 - **Projected financials**
- **One of its main purposes is to raise money-** be realistic but not fatalistic (the plan will change over time)



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Create THE BOARD



The Board of Directors

- Represents the shareholders
- Hires the CEO and sets comp
- Controls all stock/option issuance
- Approves the budget
- Acts as a resource for management

A good Board is a great asset for fundraising

- 3-7 members
- Different strengths
 - Fundraisers
 - Industry leaders who can help you

Chemistry is important

Learn how to run a Board meeting



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24

“Who’s going to run this business?”


HOW TO BECOME A CEO

- Have wide and varied business experiences
- Have a proven track-record of success
- Can use both wisdom and empathy to make difficult decisions
- Be energetic, but calm under pressure
- Have the ability to create and implement vision and direction


Robert Half
Talent Solutions



- Investors are betting more on the Management Team than the product
- If you are a doctor/scientist without business experience, initial the answer is “Maybe you.” When sales start- it’s probably “Not you”
- Management requires experience and charisma
 - Industry experience
 - Sales experience
 - Start-up experience
 - ✦ Funding connections



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Companies Don’t Fail



They Run Out of Money



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Raising Money: The Stages

	Amount	Sources	Valuation
At Founding	\$1MM	Founders and Friends, SBA/DoD	\$1-10MM
Seed	\$1-7MM	Angel Investors, Small Funds, Family Offices	\$3-20MM
Series A	\$10-30MM	Venture Capital, Private Equity, Corporate Partners	\$10-40MM
Series B	20-100MM\$	Venture Capital, Private Equity, Corporate Partners	\$50-200MM

- SBA and DoD grants are a terrific source of limited funds,
 - but it takes months-year to obtain, and the initial amount is small (<\$100K at first, then up to \$1MM)
 - It's a grant- no equity is given

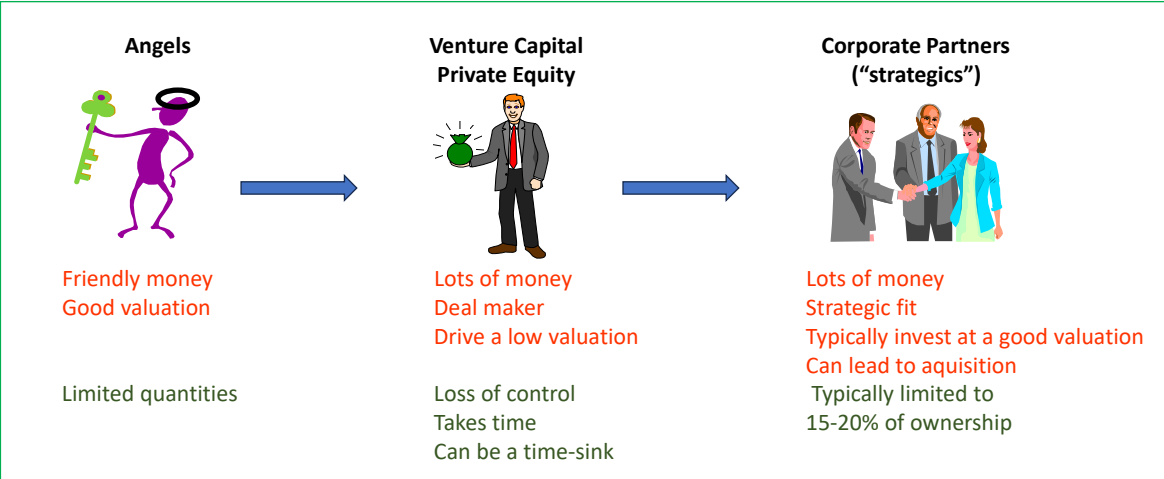


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Different Types of Money



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Company Equity Structure: Shares

At Founding, the Company authorizes a total number of shares
(e.g. 10 million)

Founders sell themselves “Founders Shares” (e.g. 5 million @ \$0.01/sh)

Founders’ shares have special tax treatment on company sale

Take a lot of shares initially- you have one chance

The remaining shares are reserved for sale (5 million)

To raise money, company sells some of the remaining shares

The share “price” is arbitrary and based on the company’s valuation

Share price – Valuation/#shares issued

\$5,000,000 valuation/5,000,000 shares issued = \$1/share



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Raising Money Is Hard

Initial investment rounds usually start with a Private Placement Memorandum (PPM) for accredited investors

Legal document that outlines amount being raised, the valuation/share price, the business plan, and the risks

You write the plan, the lawyer writes the rest

You find investors and show them the Deck and PPM

It’s a Negotiation- Expect Pushback on Valuation




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The Pitch DECK

Team


We have background, proven track record and vision to succeed




Darrin Warner
CEO



Phillip Mann
COO



Katherine Kim
CTO



Sylvia Estrada
CMO

30 Years
Management experience

\$100 Million
In acquisitions and investments

Deep Knowledge
in marketing and growth strategy

LinkedIn


Google

Prezi


CHASE

base templates.com

- Every Fundraising has a PowerPoint Deck
- No more than 20 slides (preferably 15)
- Tell your compelling story
- Pump the market need and market size
- Emphasize management
- Forward Financials
- Exit Strategy- how they will make money
 - 10+X
- Style, glitz, and name-dropping count
- **Get help with this**




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Negotiating for Money

- Objective facts sell
 - Independent market research
 - IP- patents and applications
 - Verifiable financial projections
 - Experimental data
- Names sell- someone they can call
 - Management team
 - Board of Directors
 - Scientific Advisory Board
- Give them something to look at
 - Prototypes make it real





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How Much Is Your Company Worth?

For startups, valuation is not a science

Generally, the value of the Company is determined by:

- 5-10 year **financial forecast**

- The risk of the investment – **the management team**

- The prevailing **business conditions** (interest rates, capital availability)

Early investors need to see a potential 10X+ return because most early investments fail

If you invest in 10 companies and 8 fail, but 2 return 10X, your return is 2X



You Have to Sell Your Valuation



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Valuation Exercise

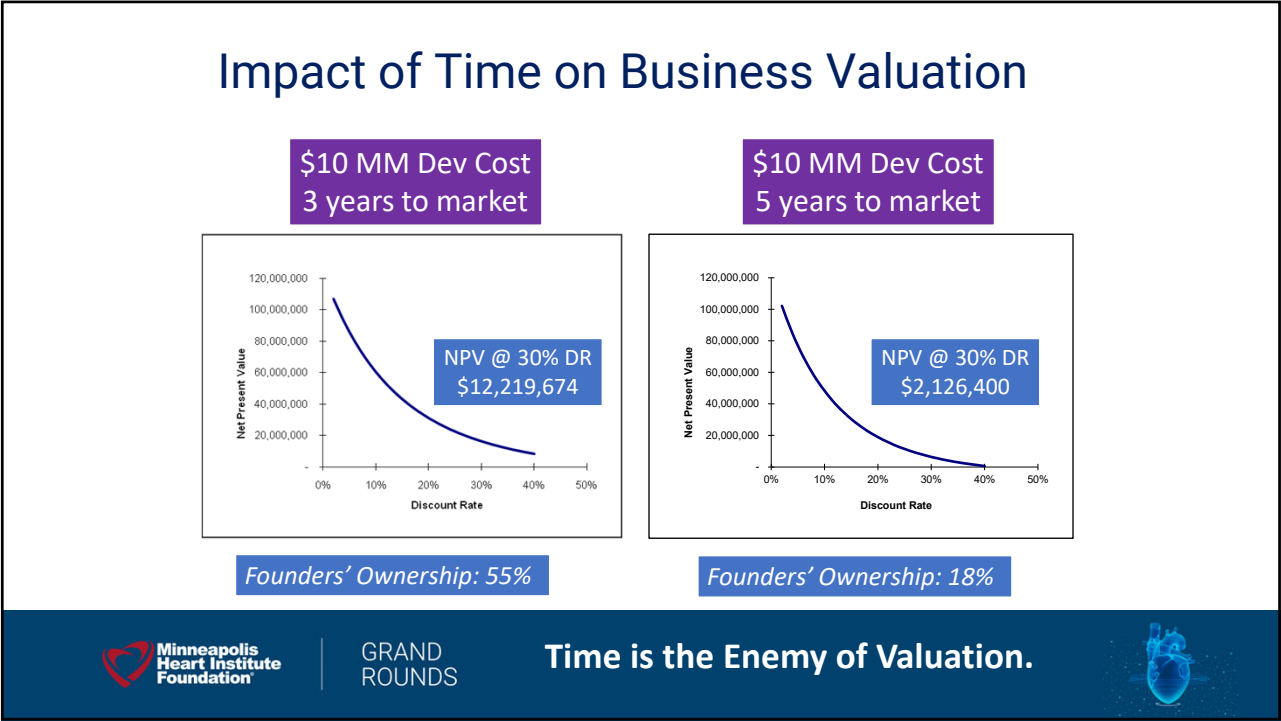
- An inventor has an idea for a medical device and starts a business
 - It's a risky idea, but probably will work if they can design it and figure out how to make it
 - Will take 3 years to get to market
- The device has a \$100 MM potential market and when manufactured will have net earnings that are 20% of sales.
- The overall investment to commercialize the device is estimated to be \$10 MM.
- What is the idea worth right now?



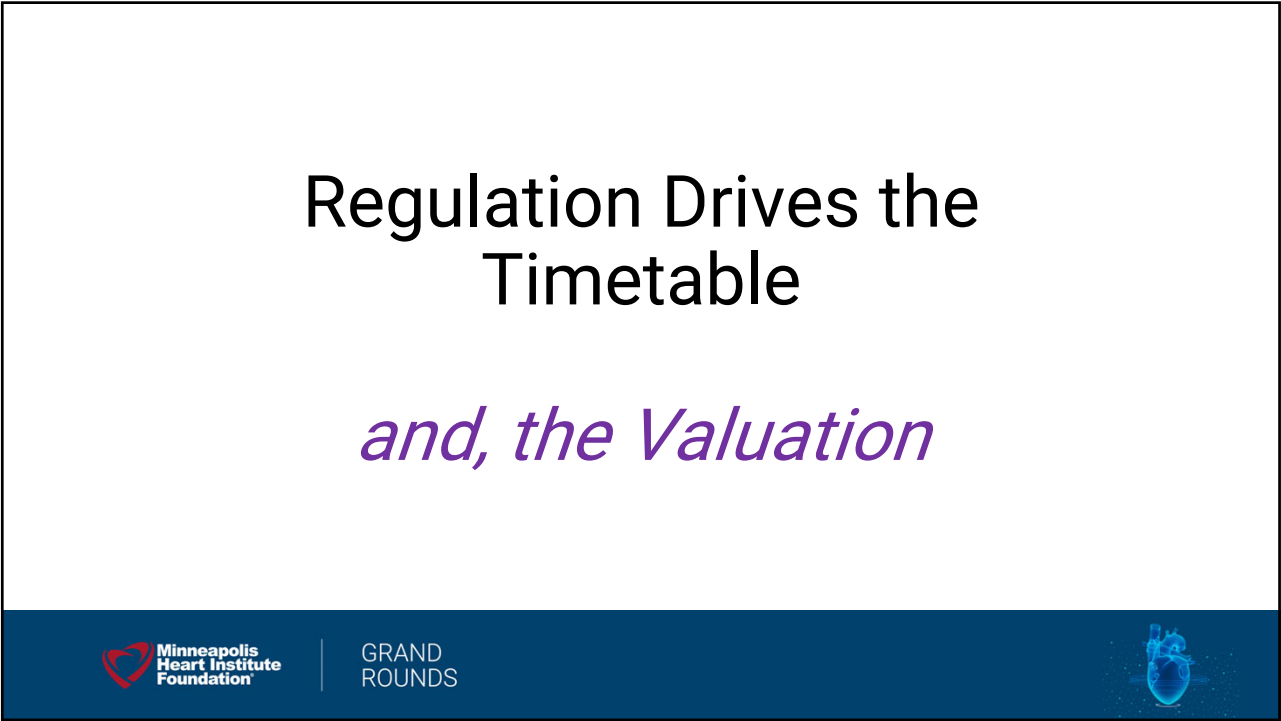
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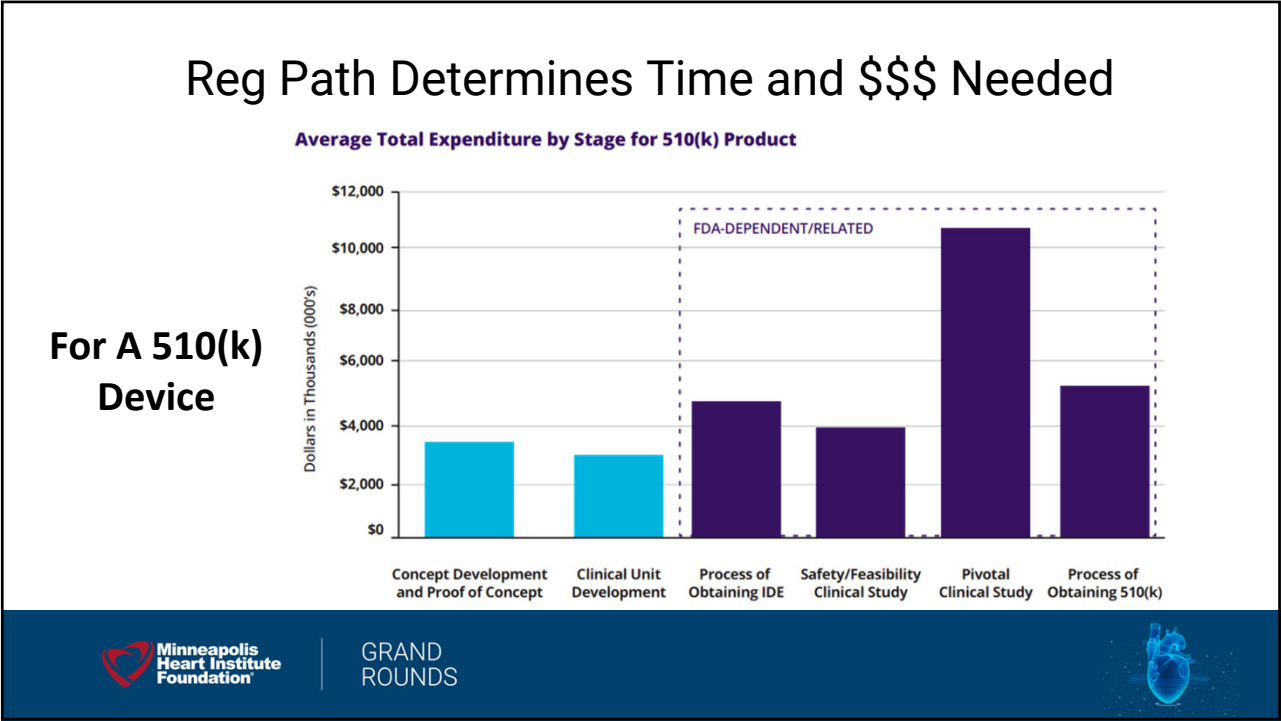
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Regulatory Strategy

The processes of device development and manufacturing are highly regulated

- ISO 13485
- FDA, UL, FCC, ANSI, AAMI...
- GLP, GCP, GMP...

Get a regulatory consultant

- Develop a strategy (e.g. is it a 510K v. PMA)
- Have a quality system in place early on
- Identify a Notified Body for ISO certification in the EU

Minneapolis Heart Institute Foundation | GRAND ROUNDS

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Security Laws and You



- There are a large number of security laws.
- If you incorporate and sell stock, you need a good lawyer
 - ❑ Experience in small business start-ups



Oh, one more
thing....

You have to SELL it!



Sales Organizations are Very Expensive

- The majority of the total capital raise will often go to building a sales organization
 - Salaries and bonuses
 - Travel
 - Sales tools like Salesforce.com
- Recruiting an EXPERIENCED Sales VP is critical
 - Doctors are lousy salespeople
- You may need to change sales leadership as the company grows and changes



41

What's the Exit Strategy?

Somewhere there has to be liquidity

- Sale to a larger company
- IPO

Investors are looking for a payout- not dividends



42

You Gotta Pivot!

There is always a twist in the road
Something fails
The market hates something you make
Economic disaster



43

**“If you really
look closely,
most overnight
successes took
a long time.”**

-Steve Jobs-

Persistence, the willingness to
accept a new reality, and the
ability to adapt are the keys.



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