Why Does Minnesota Have So Many Cardiovascular Medical Device Companies?

The base was started by Dr. Owen Wangensteen, 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.
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
Investments In IDEAS Are Less Common
Successful “Exits” Are Uncommon

Med Device 2015
- Startups with Seed funding round: 127
- Total “exits” 123
  - IPO 18
  - Acquisition 105


There Are No Rules
What Work, Works
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?

Companies Start in Stages

**IDEA (!)**
- Non-Specific Screwing Around Phase
  - Define “IT”
  - Make Frankenstein Prototypes
  - Develop and File IP
  - Understand the Market Players
  - Figure Out Regulatory Path
  - Quality System
- Real Product Development
- RAISE MONEY! Minimize Spending! RAISE MONEY! Minimize Spending!
“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%*

---

**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

---

I’ve got a new idea

Great. If it is really new and useful (and not obvious), I’ll give you 20 years of exclusive use in return for telling me how to do it.
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

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
Simplified Medical Device Regulation

FDA Device Class

<table>
<thead>
<tr>
<th>Class 1 - low risk</th>
<th>Class 2 - moderate risk</th>
<th>Class 3 - high risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low risk - tongue depressor, needle, drape...</td>
<td>Monitor, catheter, syringe, gloves, injector, ventilator...</td>
<td>Implants, life-sustaining: heart valve, pacemaker, stimulators...</td>
</tr>
</tbody>
</table>

FDA Pathway

- **Self certify**
- **Notification**
- **510(k) - predicate device or de-novo**
  - Bench data, may require some clinical data
  - 6-12 months review time
- **PMA**
  - Pivotal clinical study (2-4 years)
  - 1-4 years review time

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 = 37,361,500
- 37,361,500 x 2.8 catheters/case = 104,592,300
- 37,361,500 x $20/catheter = $747,230,000/year
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

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)
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

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
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

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
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)

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
“Who’s going to run this business?”

- 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

Companies Don’t Fail

They Run Out of Money
Raising Money: The Stages

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

- 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

Different Types of Money

<table>
<thead>
<tr>
<th>Type</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angels</td>
<td>Friendly money, Good valuation, Limited quantities</td>
</tr>
<tr>
<td>Venture Capital</td>
<td>Lots of money, Deal maker, Drive a low valuation</td>
</tr>
<tr>
<td>Private Equity</td>
<td>Loss of control, Takes time, Can be a time-sink</td>
</tr>
<tr>
<td>Corporate Partners</td>
<td>Lots of money, Strategic fit, Typically invest at a good valuation, Can lead to acquisition, Typically limited to 15-20% of ownership</td>
</tr>
</tbody>
</table>
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

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
The Pitch DECK

- 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

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
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

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?
Impact of Time on Business Valuation

$10 MM Dev Cost
3 years to market

$10 MM Dev Cost
5 years to market

Founders’ Ownership: 55%

Founders’ Ownership: 18%

Time is the Enemy of Valuation.

Regulation Drives the Timetable

and, the Valuation
Reg Path Determines Time and $$$ Needed

For A 510(k) Device

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)
AHave a quality system in place early on
Identify a Notified Body for ISO certification in the EU
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

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*
You Gotta Pivot!

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

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

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