

MEDICAL DEVICE BOOT CAMP

APRIL 28, 2010
BOSTON, MA

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PROGRAM AGENDA

CORPORATE, IP & REGULATORY FUNDAMENTALS FOR THE MEDICAL DEVICE ENTREPRENEUR

Time	Presentation	Speakers
8:00 am	Welcome and Introductions	Larry Wittenberg <i>Goodwin Procter LLP</i>
8:00 – 8:45 am	Session One: Eight Great Mistakes Entrepreneurs Make	John Brooks <i>Reflectance Medical</i> Michael Bison <i>Goodwin Procter LLP</i>
8:45 – 9:30 am	Session Two: Device Development and the FDA: What You Need to Know	Joseph Gulfo <i>Electro-Optical Sciences</i> Mark Heller <i>Goodwin Procter LLP</i> Louise Howe <i>Goodwin Procter LLP</i>
9:30 – 10:15 am	Session Three: Understanding and Protecting Your Intellectual Property	Andy Sennett <i>Soteira Inc.</i> Chris Stamos <i>Goodwin Procter LLP</i>
10:15 – 11:00 am	Session Four: Funding Sources and Strategies: From SBIR and Angel to Venture Capital and Beyond	Amy Fredrick <i>MassMEDIC</i> Aaron Sandoski <i>Norwich Ventures</i> Ray Zemlin <i>Goodwin Procter LLP</i>



Eight “Great” Mistakes Entrepreneurs Make

Medical Device Boot Camp

Corporate, IP and Regulatory Fundamentals for Medical Device Entrepreneurs

April 28, 2010
Boston, MA

John Brooks
CEO, Reflectance Medical

Michael Bison
Partner, Goodwin Procter LLP

Eight “Great” Mistakes Entrepreneurs Make

1. Complicating the Company Formation Process

- › Choice of entity (corporation vs. LLC)
 - › S corp vs. C corp?
 - › Where to incorporate?
 - › Beware of angel investors more focused on their tax break than your company.
- KISS principle should apply. Focus should be on building your business, not administrative complexities.

Eight “Great” Mistakes Entrepreneurs Make

Continued

2. Failing to Choose the Founding Team Carefully

- › How many “founders”? Ideally more than one.
 - › Roles should be clearly defined.
 - › Pick advisors that *complement* the team and add value.
 - › Scientific advisors are critically important – they should not only validate the science but also the commercial opportunity (i.e. they are future customers).
- Build a team, meet regularly, promote mutual accountability and work towards a common goal.

Eight “Great” Mistakes Entrepreneurs Make

Continued

3. Failing to Pay Attention to Corporate Formalities

- › You chose a corporate structure for a reason – make sure you realize the benefits by keeping up with the paperwork.
- › Document equity awards in a timely manner; put in place vesting schedules; file 83(b)s.
- › Consider stockholder agreements (voting/ROFR/cosale); avoid giving any one co-founder veto power over your collective destiny
- Give corporate and legal matters the same respect as your lab notebooks/engineering documents.

Eight “Great” Mistakes Entrepreneurs Make

Continued

4. Falling In Love with the Science

- › Remember you are building a business. Thus, your company must solve a significant business problem (i.e., an unmet clinical need) for which customers will pay (and payors will reimburse).
- › Fundable companies do not not serve niche markets.
- › Market research is critical: Who are your customers? Who are your competitors? What is the path to market? How will your product be marketed and sold? Who are your likely acquirers?
- Investors don’t fund science projects. They will assume the technology works and the IP is airtight. Your job is to convince them this is a viable business that will deliver an attractive return on their investment. Make the business case.

Eight “Great” Mistakes Entrepreneurs Make

Continued

5. Failing to Completely Understand the Path to Commercialization (and What it Will Cost to Get There)

- › You must completely understand the clinical, regulatory and commercial path and be prepared to defend it. (PS - you don't have to be right.)
- › What will it cost to get you from A to B? What are your milestones? Think of these as “valuation inflection points”.
- There is no “right” answer to the question: “How much are you looking to raise?”

Eight “Great” Mistakes Entrepreneurs Make

Continued

6. Undue Concern About Loss of Control and Valuation

- › It takes a team to build a successful venture.
 - › It also takes capital, and investors will want their say.
 - › Usually, loss of “control” is the cost of bringing in a high-quality investor. Noam Wasserman (HBS) calls this the “Rich versus King” founders’ dilemma.
 - › Remember that high quality investors are more than just a check book – the good ones are company builders, and their experience and guidance is valuable.
- Focus on winning before worrying about your share of the win.

Eight “Great” Mistakes Entrepreneurs Make

Continued

7. Failing to Raise Enough Money (or Spending the Money You Raise Too Quickly)

- › Everything will take twice as long and cost twice as much as you probably think.
 - › Focus should be on equity appreciation and not salary / bonus. (And don't even think about asking for founder “buy outs”.)
 - › Also, undue concern about “dilution” will likely come at the expense of product development timeline. If the money's there, take it. Raising money is hard.
- General rule is raise as much as you can, when you can, and make it last as long as possible.

Eight “Great” Mistakes Entrepreneurs Make

Continued

8. Waiting for Guffman

- › Do not assume you have all the answers and the money will just find you.
- › Get good advice. Take careful notes. Network! Iterate.
- › At the same time, remember the three “Ps”: perseverance, persistence and passion – these above all others are what separate the winners from the losers.
- Building a business is hard work. You don’t have to convince everyone, but you need to try.
- Build a strong team, get good advice, stick with it. Good luck!

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Thank you

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Device Development and the FDA: What You Need to Know

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Device Regulation Today

- Transition
- Uncertainty
- Effort to standardize practices
- Supervisory oversight
- Critical to plan and know what you are doing

- What are the First Five Things You Should Consider When Seeking to Market a Medical Device?
 - › Determine regulatory pathway
 - › Form a submission team
 - › Devise a regulatory strategy
 - › Staying power
 - › Build a robust regulatory and quality organization

What are the First Five Things You Should Consider When Seeking to Market a Medical Device?

- **Determine Regulatory Pathway**
 - › Determine the regulatory status of your device
 - Exempt
 - 510(k)
 - de novo
 - PMA
 - IDE
 - › If uncertain
 - 513(g)
 - OCP

What are the First Five Things You Should Consider When Seeking to Market a Medical Device?

- **Form a Submission Team (Should be first act, almost never is)**
 - › Build an in-house regulatory/quality team
 - › Retain
 - Consultants
 - Counsel

What are the First Five Things You Should Consider When Seeking to Market a Medical Device?

■ **Devise a Regulatory Strategy**

- › 510(k)s
 - Predicates – indications and technology (data needed to bridge technology differences)
 - Review route -- traditional review, abbreviated 510(k), or third party review
 - Pre-IDE/submission meeting
 - Just submit
- › PMAs
 - Pre-IDE
 - Pre-submission meeting
 - 510(k) implants and PMA devices - binding agreement meeting
 - Expedited review
 - Lining up expert support
 - Clinical
 - Pre-clinical
 - Statistical
- › IDEs – SR/NSR

What are the First Five Things You Should Consider When Seeking to Market a Medical Device?

- **Staying power – ability to sustain a campaign**
 - › Timelines for each major activity to work against/establish milestones
 - › Ability to respond to 510(k) AI/NSE Questions/PMA deficiency letters/not approvable letters
 - Answer inquiries
 - Informal resolution of differences
 - Meetings
 - Then respond
 - 10.75 – Supervisory review
 - Dispute resolution – Section 562 FD&C Act/Guidance

What are the First Five Things You Should Consider When Seeking to Market a Medical Device?

- **Build a robust regulatory and quality organization**
 - › FDA focused more than ever on postmarket
 - › Major considerations
 - PMAs – need successful inspection for approval
 - 510(k)s – first product, likely inspection within first 6 to 18 months
 - Recalls
 - Reporting – major focus
 - PMS – both PMAs and 510(k)s

Summary

- Uncertain environment
- Must know your rights and the agency's procedures
- Must be well prepared to sustain an effort, particularly in the PMA context
- Must maintain patience and wisely negotiate and use available appeal mechanisms
- Even now, companies are generally successful bringing devices to market, but it is taking longer and costing more

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Thank you

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Understanding and Protecting Your Intellectual Property

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IP Protection

What If I Don't Do Anything?

- You will need to rely on first mover advantage and long term contractual relationships to lock in customers
- Your competitors will adopt your technology and you will have no legal recourse
- You will have difficulty securing investors
- You will be unable to maximize the value of your business
- You will have a much longer path to profitability, if at all
- You may be sued for patent infringement and put out of business
- You may be sued for trademark infringement and forced to rebrand your product or rename your company

IP Protection

Where Do I Start?

- What aspects of my company give me commercial advantage and what would I care about, if competitors copy?
 - › company / product names and branding
 - › product technical features
 - › product design
- Are these aspects protectable?
 - › patent new, useful, and nonobvious inventions and ornamental designs
 - › copyright software code
 - › trademark names and logos
 - › trade secret manufacturing methods, black box algorithms, etc.
- Have I forfeited the right to patent or disclosed the secret?

IP Protection

What Do I Do?

- Survey the IP and commercial landscape
 - › All “prior art” is relevant to patentability
 - Even if it is patentable, it may not be worth patenting
 - do a cost vs. benefit analysis
 - consider maintaining as a trade secret, if possible
 - › Claims of third party patents may be a roadblock
 - Patents are negative rights !!
 - Analyze issued patents and watch pending applications
 - Options include designing around or licensing in problem patents, or waiting until they lapse or expire
 - › Choose company / product names to avoid conflicts

IP Protection

What Should I Do First?

- Educate yourself and develop a comprehensive IP strategy, based on legal advice about your options and your business plan
- Get non-disclosure agreements (NDAs) in place with third parties prior to business discussions
- Get IP assignment agreements (with NDA provisions) in place with all founders, employees, consultants, and contractors
- File provisional U.S. patent applications promptly
 - › prior to any disclosure outside the company, even under NDA, for core technology or to potential licensees / competitors
 - › prior to public disclosure to avoid forfeiting foreign patent rights
 - › within one year to avoid forfeiting U.S. patent rights
- Be realistic about the cost vs. benefit analysis of IP protection

IP Protection

Questions ??

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Thank you

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Funding Sources and Strategies: From SBIR and Angel to Venture Capital and Beyond

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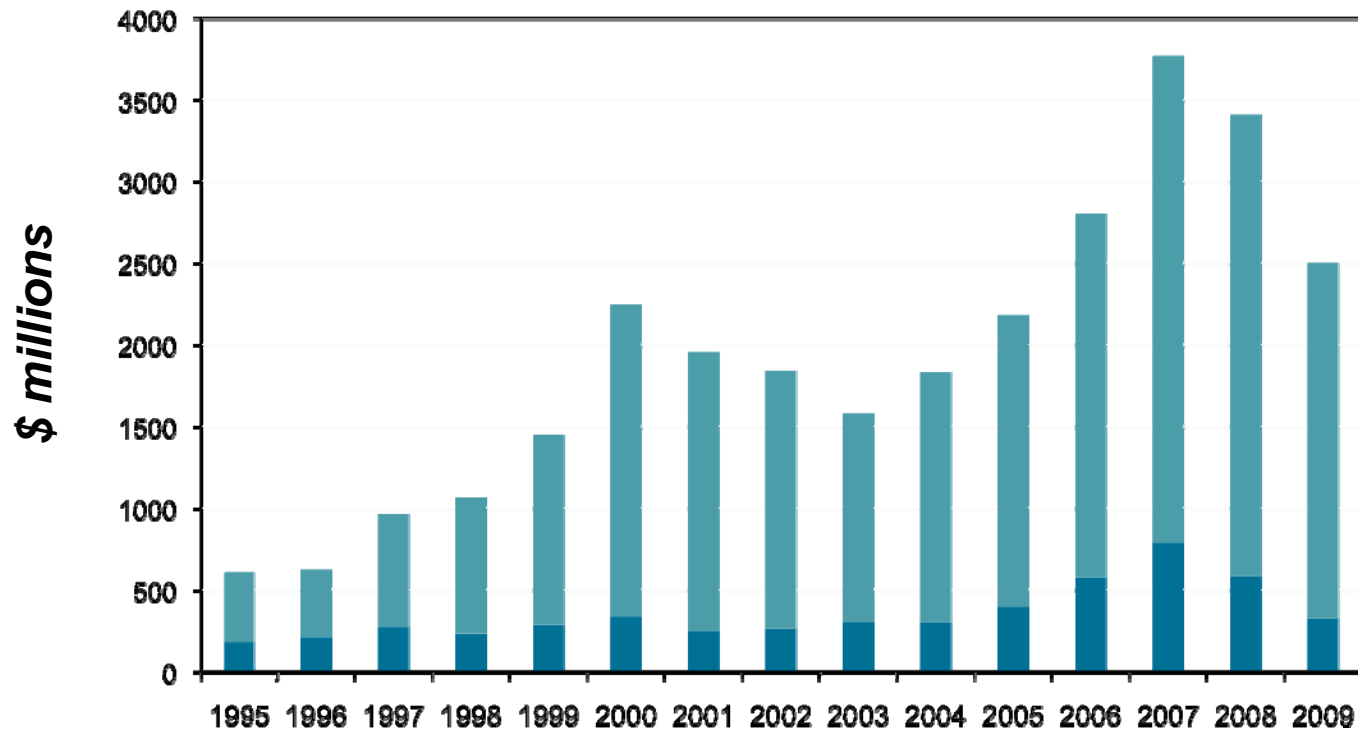
Managing Partner, Norwich Ventures

Ray Zemlin

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Venture Capital Invested in MedTech

Annual MedTech VC Investment



Source: PWC MoneyTree Report

Drivers Affecting Start-up MedTech Industry

Driver	Negatives	Positives
Healthcare Reform	2.3% excise tax starting in 2013	30 million additional insured
Venture Capital drying up	Much harder to raise capital	Less competition
Economic Crisis	Large companies reduced M&A	Non-cyclical sales has led to acquirers having cash on hand

Alternative Sources of Funding

- SBIR Grants
- State Programs including M2D2 and Massachusetts Life Science Center
- Mentoring Programs
- Friends, Family, and Fools!

SBIR Grants

- To be considered must :
 - › identify the technical barrier that is preventing commercialization
 - › describe the innovative research that your company will perform to overcome that barrier
 - › Indicate what will be measured and how good it must be to prove that you have overcome that barrier
- No barrier – no innovation – no grant!
- This is economic redevelopment money –want the money spent in the U.S.A., preferably to generate new jobs
- Key goal is new products

Who is Eligible to Apply for a SBIR Grant

To Be Eligible:

- Company must be at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States
- Independently operated
 - Control your own research space
 - Simple test: Can you lock your own door? Control the key?
- Principal place of business is on US soil
- No more than 500 employees
- For profit entity
- Able to carry out innovative research
- Own your IP

Thank you

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