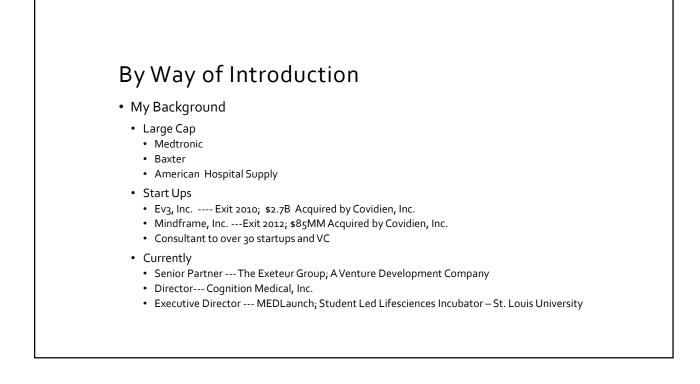
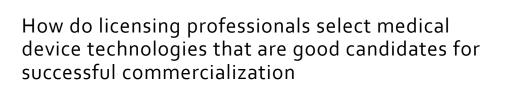
### Strategies and Programs for De-Risking Medical Device Commercialization

JOHN HARDIN ACCELON LLC – A STRATEGIC CONSULTANT TO EARLY STAGE MEDICAL DEVICE COMPANIES



### Today's Agenda

- How do licensing professionals select medical device technologies that are good candidates for successful commercialization?
- What is the general regulatory process for bringing new medical devices to market?
- What market risks and technology risks are inherent to the process of bringing new medical devices to market?
- How do reimbursement considerations effect the marketability of medical devices?
- How are market risks and technology risks assessed for potential new medical devices?
- What is the basic product development process for creating new medical devices?
- What are some specific strategies and approaches used to de-risk medical device development as one proceeds through the development process?
- What specific actions can universities take to increase the value of their medical device technologies to prospective licensees?



- Uniqueness of technology
  - Revolutionary v. Evolutionary
- Disruptiveness
  - Value Added
  - What does technology replace?
  - How do you metricize success?....outcomes? Cost efficiency?
- Market opportunity
  - Market Dimensions
    - How Large ---- \$1B; \$5B???? 100,000+ Procedures
      - Smaller Markets are still Fundable but can be more difficult to attract capital
      - Think Globally
        - WW Market dimensions are what matters the MedTech world thinks globally.
      - Growth is a key factor as well Category CAGR is important



- Pricing Structure
  - Market Average Selling Price (ASP)
  - Relative profit margins
  - Voice of the customer utilizing in-house experts
- Competition
  - Who are the competitors
    - Large Cap; Mid Cap; Emerging Companies
    - Are there a potential strategic partner/partners in the array of competitors.
- Regulatory
- Reimbursement
- Development P

### What market risks and technology risks are inherent to the process of bringing new medical devices to market?

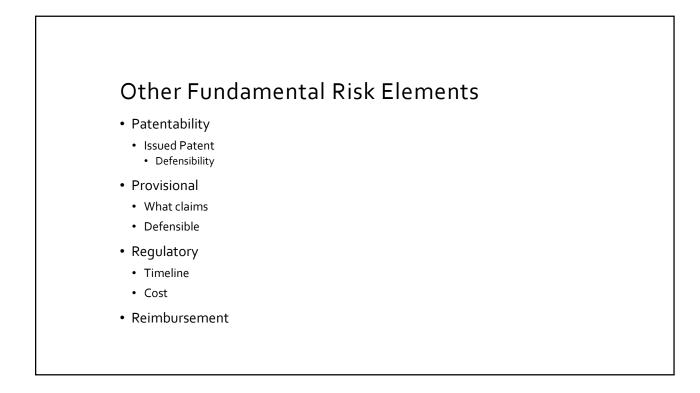
- Technology risk
  - Development timeline and cost
  - Manufacturability
    - Design challenges
    - Material challenges
    - Profit margins
  - Competitive development
- Market risk
  - Product acceptance
  - Competitive response
  - Price pressure

- Mitigation
  - Manufacturability
    - Encourage simplicity
    - Challenge inventors regarding practical considerations...profit etc.
  - Market Risk
    - Customer feedback
    - Competitive market map
    - Profit margins

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## What is the general regulatory process for bringing new medical devices to market?

- Regulatory pathways
  - Pre Market Approval (PMA)
    - Typically implantable devices, high level life saving devices, novel not previously approved applications
    - Likely to require randomized, prospective clinical trial
  - 510(k) Clearance Pre Market Notification
    - Class 2 devices, Devices with similar characteristics and approved indications
    - Predicate devices required
    - 510(k) De Novo Hybrid of 510(k) and PMA for truly innovative technologies
- Device Categories
  - Class 1 Low risk to patient
  - Class 2 Moderate risk to patient
  - Class 3 High risk or life sustaining
- A retained regulatory consultant is worth their weight in gold!!

## How do reimbursement considerations effect the marketability of medical devices?

- Understanding reimbursement key to success of medical devices
- Does the medical device fit into current reimbursement schemes?
  - DRGs, CPT, ASC codes
  - If answer is yes.....a good strategy for med/surg devices
- New procedures and diagnostic devices frequently require specific CMMS approval for reimbursement.
  - Process can be very lengthy and uncertain a major source of market risk for such devices
  - Potential for parallel FDA and CMMS review for disruptive technologies

### What is the basic product development process for creating new medical devices?

- Bench feasibility
- Animal feasibility
- Animal testing
  - Product Performance
  - Voice of the customer testing
  - Process validation
  - Validation and verification
- First in man studies
- Regulatory and value demonstration clinical trials

- Timeline for process
  - 2-5 years
- Process cost
  - \$1MM -----and up
     Experiential average on relatively straightforward devices = \$5-\$10MM
- Regulatory pathway can add time and cost+++ to the process
- Product needs to project 90% gross profit in out years of a five year P&L projection

## How are market risks and technology risks assessed for potential new medical devices?

RISK

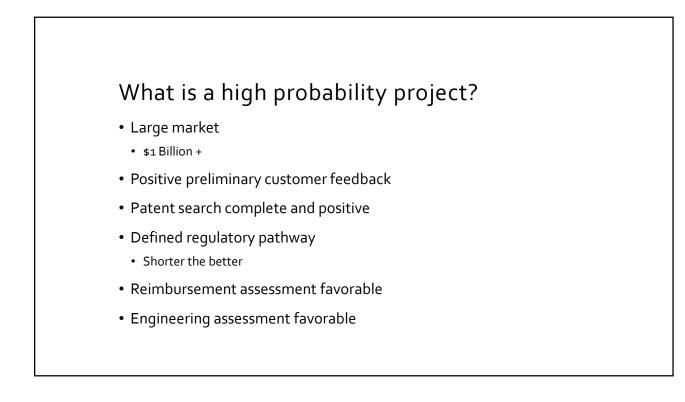
- IP
- Regulatory
- Reimbursement
- Market Risk
  - Dimension/Pricing
  - Market Acceptance
- Technical Risk

#### ASSESSMENT

- Patent search prior to provisional filing
- Regulatory consultant
- Reimbursement consultant
- Market assessment and customer interviews
- Engineering Analysis

# What are some specific strategies and approaches used to de-risk medical device development as one proceeds through the development process?

Patentability	Should rollup into provisional filing costs
Market Assessment	\$5-\$7.5K if done externally
Regulatory	\$3-\$5K Consultant
Reimbursement	\$5K
<ul> <li>Product Development Funding</li> </ul>	Grants and Internal
<ul> <li>Incremental Investment</li> </ul>	\$13-\$17.5K
<ul> <li>Investment limited to high probability projects</li> </ul>	



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