Strategies and Programs for De-Risking Medical Device Commercialization

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By Way of Introduction

- My Background
  - Large Cap
    - Medtronic
    - Baxter
    - American Hospital Supply
  - Start Ups
    - Ev3, Inc. ---- Exit 2010; $2.7B Acquired by Covidien, Inc.
    - Mindframe, Inc. ---Exit 2012; $85MM Acquired by Covidien, Inc.
    - Consultant to over 30 startups and VC
  - Currently
    - Senior Partner --- The Exeteur Group; A Venture Development Company
    - Director--- Cognition Medical, Inc.
    - Executive Director --- MEDLaunch; Student Led Lifesciences Incubator – St. Louis University

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?

How do licensing professionals select medical device technologies that are good candidates for successful commercialization

- 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

- Market Opportunity
  - 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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Other Fundamental Risk Elements

- Patentability
  - Issued Patent
    - Defensibility
- Provisional
  - What claims
  - Defensible
- Regulatory
  - Timeline
  - Cost
- Reimbursement

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
• Product Development Funding	Grants and Internal
• Incremental Investment	$13-$17.5K

- Investment limited to high probability projects

What is a high probability project?

- Large market
  - $1 Billion +
- Positive preliminary customer feedback
- Patent search complete and positive
- Defined regulatory pathway
  - Shorter the better
- Reimbursement assessment favorable
- Engineering assessment favorable

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