Plenary Roundtable

Medical Device Development: An Industry-Academia Joint Venture

Dr. Dorin Panescu
St. Jude Medical, Sunnyvale, CA, USA

SATURDAY, AUGUST 23
1:00 pm – 2:00 pm
Panelists

- **Academia Panelists:**
  - Dr. John Pearce – University of Texas at Austin.
  - Dr. Nitish Thakor – The Johns Hopkins School of Medicine

- **Industry Panelists:**
  - Dr. Mark Kroll - Prolific inventor, co-founder of start-ups.
  - Reese Terry, M.S.E.E. - Co-founder of Cyberonics, Inc.

- **Intellectual Property Attorney:**
  - Dr. Steven Mitchell – Chief Patent Counsel, St. Jude Medical, Inc., Cardiac Rhythm Management.
Reason for this Roundtable

- In recent years, the Industry has become bottom-line oriented
  - Basic research funding cut
  - Focus on new product commercial releases
  - New clinical indications
  - Cost cutting

- Basic research and more risky new product development done more at ‘start-up’ level than at ‘established-company’ level

- Academia suffers from research fund growth
  - NIH funding kept at zero-growth for several years (meaning actual NIH budget decrease after factoring for inflation)
  - Whitaker funding exhausted

- Industry can benefit from basic research conducted at Academic centers

- Academia can look for additional funding from the Industry to make up the shortfall from current funding sources
Presentation

– Dr. Pearce will address topics related to:
  • How to overcome academia-industry partnership hurdles?
  • What is the academia value for the industry?
  • What is the industry value for the academia?

– Mr. Terry will cover critical items related to starting up a company:
  • The process of founding a company
  • Expectations of an early-stage and of a mature company
  • Collaboration between academia and entrepreneurs in starting companies

– Dr. Thakor will discuss entrepreneurial aspects in academic life:
  • Clash of cultures: Industry vs. Academia?
  • What obstacles academics may face in reaching entrepreneurship?
  • Positive aspects of getting involved and succeeding as an entrepreneur: What is the winning formula?

– Dr. Kroll will address product development maps:
  • Steps to turn an idea into a medical product?

– Dr. Mitchell will address IP issues and concerns:
  • How are patents used by companies?
  • Working with universities: Benefits and hurdles in IP co-development. Alternative options for the industry.
  • Gender differences in patenting in the academic life sciences.
John Pearce

BME Track Adviser
Undergraduate Adviser
Electrical & Computer Engineering
The University of Texas at Austin
Academic Value for Industry: Upside

Problem Analysis:
- Thorough investigation of the governing principles,
- Careful study in an area of specific expertise,
- Benefit of (often) years of investigation of a single problem.

Consulting arrangements are often the most effective means of collaboration.

Sometimes we have a good idea;
- Intellectual property issues can be a sticking point.
Downside

- Intellectual Property Issues can be a sticking point.

- Results are slow to come:
  - Minimum student project increment = 1 semester,
  - Students have a lot of other things to do,
  - Students are not experienced.
Industry Value for Academia

■ Valuable Source of Real World Problems:
  – Vibrant and vital look at issues of current relevance,
  – Gives students a glimpse into professional activities and endeavors,
  – Helps us maintain a sense of perspective.

■ We get a strong sense that it is all worthwhile:
  – Can translate into effective classroom examples,
  – Clear indication that classroom material is important and useful.
Industry Contributions to Academia

- Highest Possible Value:
  - Hire our graduates,
  - Support our Graduate Students’ Research.

- Very High Value:
  - Real world design problems,
  - Meaningful internship / externship experiences.

- High Value:
  - Active participation on advisory committees,
  - Feedback on curriculum issues.
Starting A Company

An Industry-Academia Joint Venture

Reese Terry, Founder, Cyberonics
EMBC 08 Vancouver
August 23, 2008
Forming a Company With Academic Ties: Considerations

- Will the institution permit the academician to collaborate with industry?
- Is the intellectual property strong, and are all the parties able to use it?
- How big is market opportunity?
  - $350 - $1 Billion per year to attract VCs
  - Is the need for the product both compelling and unmet?
- How original is the technology or product?
Forming a Company With Academic Ties: Considerations

- How solid is the management team?
- How realistic is the business model?
  - What is the feasibility of developing and manufacturing the product?
  - How long, costly, and risky are the planned clinical trials?
  - What tradeoffs are involved with the enrollment criteria?
  - What are the reimbursement hurdles and payment levels?
  - What risks are involved in the marketing plan?
Questions

- Is it better to start a new company or out license the technology?
- Is the academician ready to give up control of the project and publications?
- Should the academician stay in academia or jump to the start-up?
- Is the academician an asset or liability to the company?
- Is this product a high priority for the company or will it be mothballed?
Tech Transfer Issues

- Push out the technology for the betterment of mankind or maximal return to the institution?
- Allow free use in underdeveloped counties, (e.g., AIDS drugs)?
- Share royalties with inventors and departments to encourage disclosures?
- Structure deals for start-ups vs. established companies?
- Develop strategies for future corporate partnerships?
- AUTM – Association of University Technology Managers
- LES - Licensing Executives Society
Fund Raising

- Develop a business plan
- Identify a management team
- Develop milestones and funding requirements for commercialization

Funding sources
- Government grants – DARPA, SBIR, NIH
- Bank loan with personal guarantee
- Friends, family, angel investors
- VCs
- Corporations
- Customers
Collaboration Between Academia and Entrepreneurs

- Basic science
- Instrument, device, or procedure development by clinician
- Proof of concept studies
- Scientific advisory board membership
- Animal study design and conduct
- Clinical study design and conduct
Collaboration between Academia and Entrepreneurs

- Safety studies
- FDA-required engineering studies, (i.e., EMI or MRI)
- Advanced engineering developments
- Issues – Academic timetables may be slower than desired by the entrepreneur
- Issues – Academic interests may not align perfectly with those of the entrepreneur
Expectations of early-stage vs. mature company

**EARLY STAGE COMPANY**
- Attainment of technical milestones
- IDE approval if PMA product
- Clinical enrollments, milestones, and budgets
- FDA approval – PMA or 510K
- Reimbursement approval
- Market acceptance and growth pattern

**MATURE COMPANY**
- Growth and profitability
- Competitive prospects
<table>
<thead>
<tr>
<th>Industry</th>
<th>Number of observations</th>
<th>Average royalty rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Device</td>
<td>77</td>
<td>4.35%</td>
</tr>
<tr>
<td>Pharmaceutical</td>
<td>90</td>
<td>5.66%</td>
</tr>
<tr>
<td>Chemical</td>
<td>21</td>
<td>3.70%</td>
</tr>
</tbody>
</table>
Academic-Industry Conflicts

- National Academy of Engineering: The impact of academic research on industrial performance (medical devices and equipment studied)

- Cleveland Clinic Journal: Medical devices and conflict of interest: Unique issues and an industry code to address them by Paul LaViolette, COO Boston Scientific

- DeBakey Hailed As Greatest Surgeon Ever As Grassley Launches Investigation Into Deceased Doctor's Ties to Device Industry

- Michael Crichton Book: NEXT
Academic-Industry Conflicts

- **JAMA**: Industry practices that create conflicts of interest: Proposed guidelines
- **Senate Testimony by G. Demske**: Examining the relationship between medical device industry and physicians
- Feds crack down on medical device implant for profit industry
- **Science for Sale**: The perils, rewards and delusions of campus capitalism by Daniel Greenberg
- **AAFP (family physicians)**: Limit interface with industry, say academic leaders
Medical Device Development: An Industry-Academia Joint Venture?

Nitish V. Thakor, Ph.D.
Professor, Biomedical Engineering
Johns Hopkins University
Director, Neuroengineering Training Program
Co-Founder, Infinite Biomedical Technologies, Ikona Medical
Outline/Issues

• Academic Entrepreneur?
• Clash of cultures: Industry vs. Academia?
• Opportunities and obstacles faced by academic entrepreneurs
• Positives aspects of getting involved and succeeding as an entrepreneur: What is
• The winning formula or best of both worlds?
Academic Entrepreneur?

• **Personal story**
  – Started companies with former students
  – Significant Johns Hopkins clinical partnership
  – Strong University-industry-government partnership
  – Raised more than $20M through the SBIR program

• **Lessons learned**
  – Too much research, too little business focus
  – Reliance on govt funding vs. VC/angel funding
  – Dealing with the University (mission, conflicts, IP)
A biomedical start-up across the street from the Homewood campus—IBT—is creating lifesaving products that draw upon faculty and alumni expertise.

By Dave Beaudouin
Cortical Injury Monitor

D. F. Hanley, Prof Neurology, Dir Neuro Outcome Res

R. Geocadin, MD, Neurology, Co-Director, NCCU, BayView, JHMI

Matthew A. Koenig, MD, Fellow, NCCU/Neurology JHH

NIH SBIR Phase IIB Grant R44 HL70129
Creating Institutional Partnerships and Synergies

School of Medicine Campus  
- Cardiology
- Neuro/Anesthesiology
- Radiology
- BME

Clark Hall, Homewood Campus  
- Biotech Park
- Institute for Translational Research?

Whitaker Institute
Academic Entrepreneur?

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Clash of Cultures: Industry vs. Academia?

• University’s mission: educate, create knowledge through research, training
  – but also innovate, new technologies, translate into practice and serve the society

• Industry’s mission: to increase shareholder value through products and profits needed by society
  – but also innovate, create intellectual property, serve employees and community
Opportunities and Obstacles faced by Academics

• Opportunities
  – Freedom
  – Intellectual environment, being at the cutting edge
  – Human resources (engineers, physicians, students)
  – Physical resources (also hospital, patients)

• Obstacles
  – Conflict of interest
  – Mission priority
  – Intellectual property management by University
  – Ivory tower culture
The Winning Formula? Or best of both worlds?

- **Mission priority**: make innovation, technology development, intellectual property, and translation a priority (lab / university culture)
- **Ambiance**: Use the university’s intellectual and human resources; manage the COI and IP issues
- **Partnership**: (1) students/post-docs, entrepreneurial clinical colleagues, (2) invite in entrepreneurs, investors
- **Conventional ideas**: “Silicon Valley”/incubators-start ups around University/Govt-University-Industry partnership
- **Controversial idea**: “Give away” IP to students/faculty, open doors to inventors/investors; stimulate innovation and entrepreneurship...the rewards will come
Building BME for the Future

Multi-faceted, Multi-dimensional, Interdisciplinary-Translational Entrepreneurial
Medical Device
Development Challenges:
Some Ideas

Mark W. Kroll, PhD, FHRS, FACC

Adjunct Full Professor Biomedical Engineering, Cal Poly University
Lecturer on Creativity & Innovation, UCLA
Adjunct Full Professor Biomedical Engineering, University of Minnesota
My Favorite Subject

- 275 issued U.S. patents
- > 1 million patients with a licensed patent
- 3 public boards
- 6 private boards
- 3 books
  - ICD Therapy
  - Cardiac Bioelectric Therapy
  - Conducted Electrical Weapons
Disease Challenges

- Diabetes
  - High fructose corn syrup
  - American Diabetes Association
- Cancers
  - Kills more than heart disease up to ~75 years of age
  - Far more years of life taken
  - Research dominated by search for silver bullet drug
  - Chemotherapy recently reformed
- Asthma
Funding Challenges

- **Venture funding**
  - Favors expensive therapies
  - Already reimbursable
  - Fast return
  - Low risk
  - Client is the pension fund or university endowment

- **National Funding**
  - Dominated by AIDS research
  - SBIR
    - Many low risk incremental gadgets
Cholesterol Industry Challenge

- Statins
  - Pulling USD 20 billion annually of out healthcare
  - Helps 1 in 300 takers at best
  - Hurts large fraction with
    - Reduced energy, lethargy
    - Reduced memory, IQ
  - Significantly over-prescribed
University Model

- Positives
  - High risk projects
  - Smart and dedicated researchers
  - Publication pressure forces information sharing

- Negatives
  - Unrealistic financial expectations
  - Slow licensing departments
  - All being improved
Pelegrin-Mayo Model

- Mayo Medical School researchers develop idea
- Pelegrin Partners
  - Screens ideas
  - Finds CEO
  - Creates NewCo
  - Provides first round financing
- Mayo gets:
  - Royalties
  - Stock in NewCo
- First 2 NewCos
  - MuVe: Obesity
  - NeoChord: Mitral valve repair
University of Minnesota

- Biomedical Engineering Department
  - Senior design projects bring in smaller challenges
- Medical Devices Center
  - Built specifically for designing, prototyping, and testing new medical devices.
  - Lab features equipment that allows researchers to view live surgeries in 3D
  - CAD precision-instruments area
  - Mechanical and electronics fabrication center
- Technology Transfer Office
  - Hired seasoned VC
Institute for Engineering in Medicine

- Large Funding Grants
  - Multimodal Biomedical Imaging
  - Cell-Based Cardiac Regeneration and Repair
  - Wireless Neural Nanoprobe Development
  - Thermal Therapies and Biopreservation
  - Wireless Implantable NMR Spectrometer Development
  - Restoration of Urinary Bladder Control
  - Medical Device Design
- What if? Seed Grants
Conclusions

- Many of the challenges in medical R&D are not talked about.
- There are many creative approaches to university-industry cooperation.

Mark@krolls.org
Medical Device Development: An Industry-Academia Joint Venture?

Steven Mitchell, J.D.
Vice President, Chief Patent Counsel
St. Jude Medical CRMD
How Are Patents Used By Companies?

- **Barriers to Market Entry**
  - May be passive
  - Deter new entrants/investments

- **Large-sized companies**
  - Cross Licensing
  - Licensing Income

- **Mid-sized companies**
  - Protect market share or market niche

- **Small-sized companies**
  - Attract investment
  - Defensively
  - Offensively
Working With Universities

- **Opportunities for Industry:**
  - Access to cutting edge research
  - Funding at Universities
    - Joint Development
    - Pure Licensing
    - Purchase?

- **Hurdles on IP matters:**
  - Licensing expectations
  - Timing of decision points
  - Flexibility in License Agreement terms
Working With Universities

- Competing options available to industry
  - Start-ups as alternatives
    - Sharing of IP
    - Equity investment and acquisition are possible
    - Licensing
  - Licensing

- Observations:
  - IP collaboration works best with fundamental inventions
    - Does the invention open a new market or fundamentally change an existing market?
  - Collaboration less compelling for “improvements”
    - Will the invention expand a market, move market share or support increased margins?
    - Royalty stacking, price compression
Gender Differences in Patenting in the Academic Life Sciences

- According to *Gender Differences in Patenting in the Academic Life Sciences*, Ding, et al, female academic scientists patent at about 40% the rate of men (http://www.kauffman.org/items.cfm?itemID=726).

- Probable causes
  - Lack of exposure/contacts with the commercial sector
    - Caused by differences in the composition of professional networks
  - Perception that pursuing commercial opportunities might hinder university careers
    - Lack of collegial support
    - Lack of institutional assistance

- “Among the most senior faculty, a large gender gap persists, reinforced by women’s limited commercial networks and traditional views of academic careers.”
Thank You.