Translating Academic Concepts to Commercial Medical Products: A Complex Academic/Industrial Partnership

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Coury Consulting Services

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Industrial Session:
The Academe-Industry Partnership

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Focus: Medical Product Development
Outline

- Medical Product Costs, Development Protocol
- Medical Product Resourcing: Hypothetical Case
- Product Selection Criteria
- Concluding Remarks
Development Costs
Pharmaceuticals/Biopharmaceuticals

15 Years

Post-Approval:
73% Need Additional Studies
30% Recoup Development Costs

Candidates

0 2 4 6 8 10 12 14

Years

Lead Discovery

10,000

Safety & Efficacy in Animals

250

Safety & Efficacy in Humans

10

Regulatory Approval

1

$1.5B

Center for Study of Drug Development, Tufts University, 2003 - 2005
Typical Development Costs for New Class III Medical Device (Rough Estimate)

- Preclinical Costs - $10-$20M
- Clinical/Regulatory Costs - $20-$40M
- Sales, Marketing, Finance, Etc. - $10-$20M
- Manufacturing Development - $10-$15M
- Total Costs to Launch - $50-$95M

Timescale: 5-10 Years

## Efficiency of Corporations, 2011

(Net Cost Per Employee for Operations)

<table>
<thead>
<tr>
<th>Firm</th>
<th>Revenues (R)</th>
<th>Net Earnings (E)</th>
<th>Employees (#)</th>
<th>2011</th>
<th>2009</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic</td>
<td>$15.9 B</td>
<td>$3.1 B</td>
<td>45,000</td>
<td>$285,000</td>
<td>$327,000</td>
<td>$297,000</td>
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<tr>
<td>Boston Sci.</td>
<td>$7.6 B</td>
<td>$0.44 B</td>
<td>24,000</td>
<td>$298,000</td>
<td>$354,000</td>
<td>$354,000</td>
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<tr>
<td>C.R. Bard</td>
<td>$2.9 B</td>
<td>$0.33 B</td>
<td>12,100</td>
<td>$212,000</td>
<td>$188,000</td>
<td>$176,000</td>
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<tr>
<td>J&amp;J</td>
<td>$65.0 B</td>
<td>$9.7 B</td>
<td>117,900</td>
<td>$469,000</td>
<td>$351,000</td>
<td>$435,000</td>
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<tr>
<td>(Genzyme**)</td>
<td>$4.0 B</td>
<td>$0.32 B</td>
<td>10,000</td>
<td>$368,000</td>
<td>$371,000</td>
<td>$406,000</td>
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<tr>
<td>Amgen</td>
<td>$15.3 B</td>
<td>$3.7 B</td>
<td>17,600</td>
<td>$659,000</td>
<td>$560,000</td>
<td>$663,000</td>
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<tr>
<td>Novartis</td>
<td>$58.6 B</td>
<td>$13.5 B</td>
<td>123,700</td>
<td>$399,000</td>
<td>$440,000</td>
<td>$261,000</td>
</tr>
</tbody>
</table>

Focal, Inc.(1992-2001), Peak Burn Rate/Peak # Employees:~$19M/125 = ~$152,000

**Data for 2010, Last year of Genzyme independent operations**

*Sources: Corporation Websites, Annual Reports*
Product Development Pathway

- Concept
  - Discovery Research
  - Preclinical Research
    - Preclinical Development
      - Clinical Development
        - Launch
        - Post-market Support
  - Discovery

** Implementation:
- Manufacturing
- Sales
- Marketing

Design Control (ISO 13485)
Hypothetical Case:
New Biologic/Device Combination Product

Assumptions:
- Existing Delivery Matrix/ Recombinant Natural Protein (e.g., BMP-2)
- ~$200 Million Development Costs
- Initial R&D with VC, “Angel,” or Government Funding
- Initial Funding Only Covers Discovery Research + Limited Preclinical Research
- Follow-On Funding needed to Bridge Discovery → Development
Most Product Development Fails in the “Valley of Death”

- Original Academic or Corporate Investment
- Invested, Millions
- “Valley of Death”
- Potential Corporate Investment
Bridging “Valley of Death”

Bridge Requirements
- Effective Champion
- Availability of Interim Funding *
- Demonstrated Progress: Before and During Bridging
- Potential Continuation of Funding at End of Bridge

* VC, Government, “Angel,” Foundation, Corporate, University, Etc.
Translation Requirements

Rate of Progress

$ Invested, Millions

Original Academic or Corporate Investment


Corporate Investment

Time
Product Development: Selection Criteria

- Mission, Vision, Culture
- Product Mix Strategy
- Fiscal “Health,” (Finances, Stock Movements, Etc.)
- Maturity: Start-up → Mature
- Potential Adoption Curve
- Market Potential
- Reimbursement Potential
- Intellectual Property, Internal or External
- Competition
- Project Champion
- Staff Capabilities: Lab, Clinical, Manufacturing (Scalability), Sales, Marketing, Etc.
- Availability of Staff for Project, Staff Mix
- Availability of Materials, Products from Outside
- Physical Plant: Equipment, Space, Etc.
- Project Costs
- Timing Considerations: Handoffs, Funding, Regulatory, Clinical, Marketing, Etc.
- Publication Strategy
- Exit or Survival Strategy
## Strategic Product Choices

### Comparing 2 Products

<table>
<thead>
<tr>
<th>Market</th>
<th># Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Sophistication</td>
<td>High-Low</td>
</tr>
<tr>
<td>Development Costs</td>
<td>$$$-$</td>
</tr>
<tr>
<td>Regulatory Pathway</td>
<td>PMA-501K</td>
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<tr>
<td>Implementation</td>
<td>Elective-Imperative</td>
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<tr>
<td>Utilization</td>
<td>%</td>
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<tr>
<td>Unit Price</td>
<td>$</td>
</tr>
<tr>
<td>Market Potential</td>
<td>$</td>
</tr>
<tr>
<td>New Product Intro</td>
<td>Timing</td>
</tr>
<tr>
<td>Implications</td>
<td>Product Improvements, Pipeline, etc</td>
</tr>
</tbody>
</table>
Limits to Value of Academic Licenses

Comparing Academic vs. Corporate Investment

- University vs Corporate Expenditures
- Funding Sources, University vs. Company
- Contribution of University vs. Company to Intellectual Property
- Stage of Development at Time of Licensure
- Totality of Licenses for Product
- Projected Revenues and Profits at Time of Licensure
- Degree of Risk Assumption by Company
- Profitability of Product when Marketed
Product Adoption Curve

$ales

Time

Typical Successful Launch

Unsuccessful Launch

“End of Life”
Concluding Remarks

If medical product is goal:

- Be product-focused from the start
- Select product/project based on meeting **Product Development Selection Criteria a priori**
- Urgently make as much progress as possible with initial funding
- Appoint effective, articulate “Champion” to advance project, develop bridge funding, strategic partners
- Use “bridge” funding to make maximum product-oriented progress
- Collaborate with strategic partner during project transfer and for problem solving thereafter if applicable
- Have realistic expectations of state of progress and value of technology if academic-corporate transfer: Medical products may be derived from many patents
- Expect goals, project plans and evaluations to be driven by quality system (e.g. ISO 13485) imperatives in development stage
- Realize that, no matter how great the staff and promising the product, most programs change original direction, but:
- The experience, knowledge and reputations gained are never lost for future enterprises.
Thank You