Corporations: A Lever for Research and Development

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Disclosure: My Relationship with Medical Device Companies

- Geometrics®
- Gammex-RMI®
- Adac
- GE Medical
- TomoTherapy®
- Accuray®
- CPAC®
- Novelos®
- Biolonix®
- Shine Medical Technologies®
- HealthMyne®
- Accelerated Devices®

* Indicates Former or Current Board Membership
@ Indicates Founder
$ Indicates Current Relationship

The Mine and the Mill

Good ideas tend to come from academia and get implemented and refined in a company.

The University is the Mine. The Company is the Mill.
A mill won’t last long if the mine is not productive.
Resistance to University-Industrial Partnerships

- In 1996, Lee found that only 44% of faculty agreed with policy of offering technology assistance to companies.
- And only 26% of faculty thought it was OK for the university to take equity in university startup companies.
- Faculty with the least linkage to industry had the least favorable view of university-industrial partnerships.


R&D Ranking

Sources of Funding for R&D

- Total US R&D spending has constant at about 2.5% of GDP.
- US federal proportion of R&D spending fell from 1965 to 2000.
- 80%+ of R&D in our field is corporate.
Number of University Spinoffs/year in the US

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Spinoffs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1992</td>
<td>200</td>
</tr>
<tr>
<td>1994</td>
<td>300</td>
</tr>
<tr>
<td>1996</td>
<td>250</td>
</tr>
<tr>
<td>1998</td>
<td>150</td>
</tr>
<tr>
<td>2000</td>
<td>50</td>
</tr>
<tr>
<td>2002</td>
<td>100</td>
</tr>
</tbody>
</table>

Average of 1980-1993: ~200 companies/year

From Association of University Technology Managers

Divergent and Convergent Thinking: Focus is a Dimension, Not a Point

Divergent Thinking:
- Thinking Outside the Box
- Exploring Possibilities
- Brainstorming
- 1% Inspiration
- "Undisciplined", "Unfocused"

Convergent Thinking:
- Step by Step Execution
- Getting the Job Done
- Project Management
- 99% Perspiration
- "Incremental", "Boring"

Project Management Differences

University

Business
I would not consult for a company that would hire me as a consultant.

Do’s and D’Oh’s

Do = Wahoo  D’oh = Damn

Why in the World Would You Want To Do This?

- What is your motivation?
- How will you get the financing needed?
- Who owns the intellectual property?
- Do you have the time?
- Will you enjoy doing it?
- Do you have business experience?
- Isn’t there an easier way to accomplish your research ends?
Medical Physics Dept. Spin-Offs

- Lunar Corporation (Now GE-Lunar)
- Geometrics (Now Philips Medical)
- Ultravision (Now Emagion)
- Advanced Medical Publishing
- Ultravision
- Medical Physics Foundation
- Medical Imaging
- TomoTherapy (Now Accuray)
- Standard Imaging
- TomoTherapy (Now Accuray)
- ABAC
- Geometrics (Now Philips Medical)
- HealthMyne
- Sonic Foundry
- Mazess Fellowship

History of Geometrics

- 1988 – First Development to Enable Stereotactic Radiosurgery (UW First in Midwest).
- 1996 – Sale of Geometrics to ADAC.
- 2001 – Sale of ADAC to Philips Medical.
- 2014 – Development team still based in Madison.
In 1992, Starting a UW Spin-Off Was Like Pulling Teeth

- University Leaders
- Company Founders
- Clinical Colleagues

Founding of Geometrics

- UW University Hospital funded development.
- FDA prohibition on clinical use of non-cleared medical software.
- Programmer funding was cut by UW Hospital.
- UW does not take a “work-for-hire” position.
- Equity in proportion to effort on development.
- Mark Gehring and Cameron Sanders went full-time to the company.
- I and Paul Reckwerdt stayed at the UW.
- Pledged $300,000 to UW, what it cost them.
- Gave an indefinite license to UW on derivative software that was named Pinnacle.
- License has saved UW >$1 million in costs.

Pinnacle, 1994
Corporate Partnership
• Corporation gets exclusive access to IP or products in return for working capital.
• They may want an ownership interest in your company.
• They may directly or indirectly exercise great control over your company.
• Partnerships can maximize your exposure to the marketplace.
• Partnerships limit the ultimate value of your company.
• Geometrics was based on a partnership with ADAC.

Successful Product, Unsuccessful Business
• Geometrics was funded on an advance of royalties (like a textbook).
• In 1996, ADAC received FDA 510(k) and could market Pinnacle.
• ADAC controlled the marketing and we perceived a go-slow.
• With what we were going to get back in royalties we would struggle to put the improvements we wanted to put into the product.
• We sold to ADAC for ~1% of eventual sales.

History of Tomotherapy
• 1988 – First ideas at the University of Wisconsin.
• 1992 – First patents filed
• 1993 – First paper of tomotherapy published.
• 1994 – GE funds UW research project.
• 1996 – Sale of Geometrics to ADAC.
• 1997 – GE gets out of radiotherapy.
• 1998 – GE funds UW research project.
• 1999 – Received first investment.
• 2002 – Received FDA 510(k) to market.
• 2002 – First patient treated at UW.
• 2004 – TomoTherapy profitable.
• 2007 – TomoTherapy sold to Accuray.
• 2011 – TomoTherapy goes public.

Two Decades
**Founding of TomoTherapy**

- TomoTherapy was formed when GE got out of radiotherapy.
- We gave more than 1/3 of stock to the staff in my UW research group who joined the company.
- WARF tomotherapy patents were licensed.
- WARF was the first investor in company.
- WARF helped find VC investors.
- Low interest loan from the State of Wisconsin.
- SBIR grant from Federal government.
- First money raised was used to finish the version of the UW prototype with GE components.
- $250,000 gift to Wisconsin Foundation.
- First sales to Canadian radiotherapy clinics.

**Approximate Startup Budget for TomoTherapy Inc. (1998-1999)**

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal</td>
<td>10,000</td>
</tr>
<tr>
<td>Salary</td>
<td>40,000</td>
</tr>
<tr>
<td>Consulting</td>
<td>20,000</td>
</tr>
<tr>
<td>Accounting</td>
<td>5,000</td>
</tr>
<tr>
<td>Computers</td>
<td>3,000</td>
</tr>
<tr>
<td>Office Supplies</td>
<td>2,000</td>
</tr>
<tr>
<td>Rent</td>
<td>0</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>10,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$100,000</td>
</tr>
</tbody>
</table>

We were off by $50,000.

**Risk-Reward Matrix for New University Technology**

<table>
<thead>
<tr>
<th>Reward</th>
<th>Low Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Best Position, But Easy to License to A Big Company</td>
<td>Most Spin-Offs</td>
</tr>
<tr>
<td>Low</td>
<td>Low Risk</td>
<td>High Risk</td>
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### Where Existing Companies Perceived TomoTherapy

<table>
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<tr>
<th>Risk Level</th>
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<tr>
<td>High Reward</td>
<td>Best Position</td>
<td>TomoTherapy</td>
</tr>
<tr>
<td>Low Reward</td>
<td>OK, But Don’t Look for VC’s to Invest</td>
<td>Modern Role of Big Government</td>
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### Where TomoTherapy Founders Perceived Their Technology

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### VC Financing

- **Necessary evil - VC may be the only viable source when funding requirements are large.**
- **VC come in flocks and they will help you find other investors.**
- **They will be able to contribute to future rounds of financing or provide bridge loans.**
- **They can help you tune your business plan.**
- **They will be able to help with key business decisions – like a merger/acquisition or a marketing decision.**
- **They will be able to be a bridge with investment bankers.**
- **Usually their interests are aligned with your’s.**
- **TomoTherapy was VC financed ($32 M until profitable).**
Issues of Conflict of Interest

• My relationship between with the University is carefully managed by the UW Conflict of Interest committee.
• What is good for my company is not necessarily good for the UW and visa versa.
• Disclosure of the financial situation is the first requirement.
  – Disclosure to the UW
  – Disclosure in oral and written communications

Financial Disclosure

“I am a co-founder of TomoTherapy Inc. (Madison, WI) which is participating in the commercial development of helical tomotherapy.”

Do’s

• Disclosure
• Disclosure
• Get everything in writing.
• I have a letter from the WI Attorney General giving official approval of my activity.
• The Smell Test – Does it somehow stink (Entre – Manure)?
• The Newspaper Test – Imagine what a negative newspaper article would do.
Absolute D’Oh’s

• Be responsible for a clinical trial involving your company’s products.
• Be responsible for either end of a contract (written or verbal).
• Force your institution’s co-workers or students to be involved with the company.
• Limit the rights of your institution’s co-workers or students, e.g., restrict publications.

Conflict of Commitment

• When and what hats do you wear?
• You need a formal agreement with your employer on your time commitment to the company – Don’t assume “a day a week”.
• You must not do business at your employer’s place of business without compensation.
• When in doubt, your first obligation is to your employer.
• With financing of TomoTherapy I first went from a 100% appointment to a 75% appointment at the UW and finally to a 50% appointment upon IPO.
Is There a Coincidence of Interest?

• What is good for the company may also be good for your employer.
• Is the intellectual property owned by your employer and licensed to your company?
• Does a royalty or other benefit return to your employer?
• Is there a grant or a contract linking the employer and company?
• You are not the arbitrator of what is good for your employer, only your employer is.

Conflict/Coincidence of Interest Matrix

<table>
<thead>
<tr>
<th>Good for Your Company</th>
<th>Not Good for Your Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good for Your Employer</td>
<td></td>
</tr>
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Shine Medical: A Public – Private Partnership

• In 2009 Canadian NRU Reactor shut down for 15 months.
• In 2010 DOE offers cooperative agreements worth $25 M for ideas to create a sustainable US supply of medical isotopes.
• In 2011 Morgridge Institute and Phoenix Nuclear Labs partner and obtain funding and Shine Medical is formed.
• Involves UW, multiple government labs, and private entities.
• In 2013 Environmental and Construction permits were filed with the NRC.
• In 2013 Morgridge role on the project ended.
Sub-Critical Intense Neutron Emitter (SHINE)

Inherently Safer Than a Reactor

Angel Investors
- Behave like venture capitalists in most ways.
- Often have motivation to help their community.
- Have less capacity than venture capitalists.
- Best for early stage investments.
- Shine Medical received > $11 M from angel investors.
- Shine needs to find >$100 M in equity and debt financing over the next three years.
Ingredients for a Successful University

Excellent Faculty, Staff and Students

Ingredients for a Successful Business

Excellent Management and Staff

How the Field Can Help

- Promote entrepreneurship in your university.
- Teach trainees the basics needed for business:
  - Cultural differences between academia and business,
  - Understanding finance and marketing,
  - Defining user requirements,
  - Product development and regulatory affairs,
  - Scheduling – using tools like Gantt charts,
  - Useful for the working in the clinic as well.
- AAPM and other organizations in our field should partner more effectively with companies.
Conclusions

• Corporations fund 80%+ of medical physics R&D.
• Working with companies or starting a business is an efficient way to have ideas actualized.
• You should be aware of the cultural differences between universities and companies.
• You should understand your motivation before starting a company.
• There are several ways to fund the startup of a company.
• Potential conflict of interests can be managed.
• Private-public partnerships are more likely if academics have business knowledge.

Questions?