Prior biotech experience:

- Garvan Institute, Sydney
- Mater Medical Research Institute, Brisbane
- Pacific Horizon Ventures, Seattle (US)
- Cytopeia, Inc., Seattle, (US)
- ICOS Inc., Seattle, (US)
Who are you?

Academic Researcher
(investigate for the sake of scientific discovery)
or
Translational Researcher
(entrepreneur)
Today’s Topics

- What to think about in commercialising a technology, device, compound, or molecule
- Options for deals
- Types of investment/investors
Anatomy of a Researcher (past)

- Academically Curious
- Focused on single question
- Internally collaborative
- Intent on scientific methods
- Not necessarily concerned with patient applications
- Hungry
Today’s Researcher

✓ Outcome Curious
✓ Focused on single and broader questions
✓ Collaborative - externally
✓ Understands need for patient outcomes
✓ Engages in commercial equation early
✓ Still hungry!
<table>
<thead>
<tr>
<th>Target Industry</th>
<th>Time to market</th>
<th>Cost to market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blockbuster Drug</td>
<td>12 – 15 years</td>
<td>$1.0B - $1.5B</td>
</tr>
<tr>
<td>Class III Medical Device</td>
<td>5 – 10 years</td>
<td>$10M - $20M</td>
</tr>
<tr>
<td>Class II Medical Device</td>
<td>3 – 5 years</td>
<td>$3M - $5M</td>
</tr>
<tr>
<td>Software Package</td>
<td>1 – 3 years</td>
<td>$1M - $3M</td>
</tr>
<tr>
<td>Energy Drink</td>
<td>3 years</td>
<td>$1.2M</td>
</tr>
<tr>
<td>Daycare Center</td>
<td>6 months</td>
<td>$250,000</td>
</tr>
<tr>
<td>Hot Dog Stand</td>
<td>60 days</td>
<td>$15,000</td>
</tr>
<tr>
<td>Sole Proprietorship/Services</td>
<td>1 day</td>
<td>$50</td>
</tr>
</tbody>
</table>
Path to Market for Biotech

<table>
<thead>
<tr>
<th>Average risk mitigated (start)</th>
<th>Time to Complete</th>
<th>Number of Clinical Trials subjects</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preclinical: 10%</td>
<td>highly variable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 1: 20%</td>
<td>0.5 – 2 years</td>
<td>20 – 80</td>
<td>~$8k-$15k pp + $.5M supporting animal studies</td>
</tr>
<tr>
<td>Phase 2: 30%</td>
<td>1.5 – 2 years</td>
<td>100-300</td>
<td>As above + $1M for supporting animals</td>
</tr>
<tr>
<td>Phase 3: 67%</td>
<td>3.5 + years</td>
<td>1,000-5,000</td>
<td>$4k-$7.5k pp + $1.5M for animals</td>
</tr>
<tr>
<td>FDA approval: 81%</td>
<td>1.5 years</td>
<td></td>
<td>Costs highly variable, but start at ~ $1.5M</td>
</tr>
</tbody>
</table>
Be real about capability

Are you:

- Rocket scientist
- Engineer
- NASA
- Business brain
- None of the above
Assets to build

• **The importance of networks** — both scientific and commercial — find the internal champion!
• **Finding the right partner** in the commercialisation process — seek help
• **The importance of the “data package”** — the sell
• **Protect, publish, engage** — building trust
• **Breaking the taboo** of commercialisation
How to Begin

- Options
  - License
  - Spin-out
  - Co-development with commercial partner
  - Sale of IP
  - Locking it in your drawer so nobody will copy it
Licensing

- **Universities/MRI’s**
  - Most are not the right vehicle for commercialisation

- **Direct Licensing of IP**
  - To existing companies is most common
  - Arms length approach = minimal ongoing investment required by university or MRI

- **Australia’s limited size and R&D investment**
  - Limited capacity to absorb university-generated technology
  - Linkages are often established with o/s firms – think global!

- **Universities and MRI’s need to simplify this process!**
The Spin-out

- Licensing through a spinout
  - Maintain ownership and command a higher return
- Team Mix
  - Matching a strong scientific team with good business/commercial management is key
- Funding the spin-out
  - the key challenge – limited $$’s for early LS
- License Agreement Access
- Universities and MRI’s need to simplify this process!
Co-Develop with Commercial Partner

- **Strategically advantageous**
  - Commercial partner identified early with resources to commercialise
- **Funds**
  - for the research / development path
- **Access to technology and resources**
  - Ex: SOA technology/regulatory/clinical trial infrastructure
- **Human capital**
  - access to broader collaboration
- **Can involve letting go of a lot of control**
Acquisition

- **Similar to licensing but assign IP**
- **Upside**
  - Immediate $$
  - Acquirer takes all risks – and all reward
- **Downside**
  - Lower $$ versus taking longer term revenue share
  - Letting go of all IP relating to this research project
Hiding in the drawer

- **Upside** = nobody knows what you are up to
- **Downside** = nobody knows what you are up to

- **You get nothing for nothing**
Profile of an Investor
Investors

1. 4 Fs (Founders, Friends, Family, Fools)
2. Business Angels and High Net Worths
3. Venture Capital Groups
4. Private Equity Investors (Insts, Directs)
5. Strategics (Pharma, Large Med Devs)
Investors

1. 4 Fs (Founders, Friends, Family, Fools)
2. Business Angels and High Net Worth Individuals
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4. Private Equity Investors (instos, directs)
5. Strategics (Pharma, large MedDevs)

They want: to help
They provide: modest funds
Investors

1. 4 Fs (founders, family, friends & fools)
2. Business Angels and High Net Worth Individuals
3. Venture Capital Groups
4. Private Equity Investors (instos, directs)
5. Strategics (Pharma, large MedDevs)

They want: personal interest, to help, capital gains
They provide: usually <$1m, introductions, strategic and operational assistance
Investors

1. 4 Fs (founders, family, friends & fools)
2. Business Angels and High Net Worth Individuals
3. Venture Capital Groups
4. Private Equity Investors (instos, directs)
5. Strategics (Pharma, large MedDevs)

They want: capital gains
They provide: $1-50m, governance, strategic direction, operational expertise
Investors

1. 4 Fs (founders, family, friends & fools)
2. Business Angels and High Net Worth Individuals
3. Venture Capital Groups
4. Private Equity Investors (Insts, Directs)
5. Strategics (Pharma, large MedDevs)

They want: capital gains, leverage
They provide: $10m+
Investors

1. 4 Fs (founders, family, friends & fools)
2. Business Angels and High Net Worth Individuals
3. Venture Capital Groups
4. Private Equity Investors (instos, directs)
5. Strategics (Pharma, Large Med Devs)

They want: capital gains, strategic leverage
They provide: $$, in-kind, market making assistance
What are investors looking for?

- Reason to invest (returns, altruism and involvement)
- Team (management, board and investors)
- Structure for Investment (ABN)
- Viable liquidity event (exit through IPO or tradesale)
- Impeccable technology (IP and publications)
- Realistic plan (timelines and resources)
- Value
Risk Factors

Financial
• runs out of cash
• exchange rate flux

Technical
• MOA
• Manufacturing

Execution
• management
• board
• investors

Clinical
• mice vs humans
• benefits not significant enough
• therapeutic window too narrow

Regulatory & Legal
• FDA, EMEA or TGA
• IP infringement
• Contract
• Malpractice

Market
• competition
• generics
• disruptive technology
Number of new start-up companies formed 2000-2011

Number of new start-up companies formed per year by sector 2000-11

Data supplied from The National Survey of Research Commercialisation 2010-2011
Number of Licences, Options and Assignments executed 2000-2011

Figure 6: Number of LOAs executed by sector 2000-11

Data supplied from The National Survey of Research Commercialisation 2010-2011
Income from Licences, Options and Assignments executed 2000-2011

The National Survey of Research Commercialisation 2010-2011
The End Product

• Will travel many levels, with many taking a piece of the action
• Understand your limitations to take it to market
• Pick your partner carefully
• It’s expensive! Make sure your technology has commercial potential
Conclusion

• Workshop your commercial discussions early
• Draw on industry people – not just fellow researchers who have commercialised before
• Always think about the patient at the end – why do they need this?
• Evaluate your value inflections – how far should you take this before commercialising?
• Talk to your ‘exit’ partner early on – test your market opportunity!
And don’t forget

It’s a long road and not for the faint of heart!
questions??????

Department of Industry | Business

Topaz Conway
tconway@commercialisationaustralia.gov.au
+61 (0)432-632-388