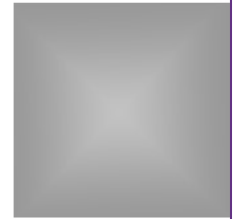


protEcol[®] Services

microbial expression experts



Process development & manufacture of
recombinant proteins and peptides

Advancing Wellness[™] ...

through the right people and the right products

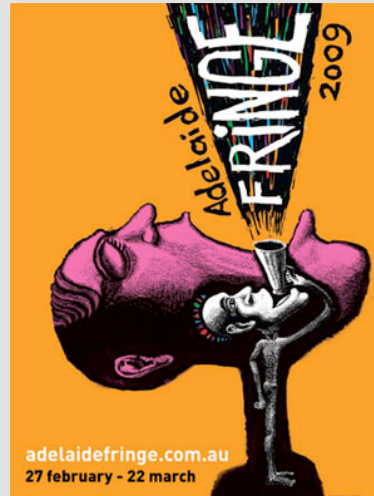


What do these all have in common?



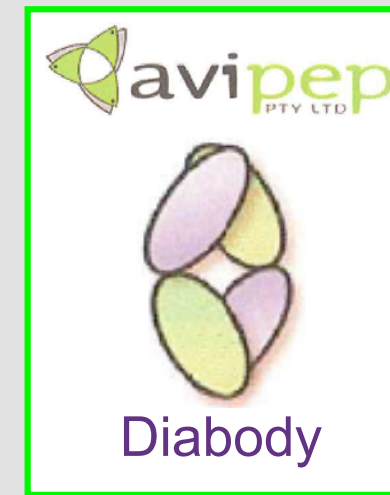
John Landis
THRILLER

14 min music video,
revolutionised pop
culture music
industry



Local Artists
EVENT POSTER

Iconic print media,
redefining the Adelaide
Fringe Festival every
year



protEcol[®] Services
PROTEINS

Pioneers in Ab fragments,
redesigned R&D
manufacturing process
for clinical use

Outsourcing

Outsourcing is procuring services, processes or products from an external supplier

- Outsourcing tasks
 - Nothing new

Outsourcing Knowledge

... A Paradigm shift

Outsourcing process development & manufacturing of biopharmaceuticals

Benefits of Outsourcing

1. Reduction in COGS
2. Economic Efficiency and Opportunity Cost
3. Technical and Operational Capabilities
4. Strategic Fit and Risk Mitigation

1. Reduction in COGS

- Drug development: ~8 -13 years
- Development cost of biologic:
US\$600 million - \$1.2 billion

Development cost of small molecule:
US\$250 million - \$850 million

- Cost of new biologic manufacturing facility
US\$250 million - \$1.0 billion
up to 5 years?

1. Reduction in COGS

- 2 key elements that drive COGS

- Molecular complexity

- Quantity required

Both determine choice of production system

- Can the company support the necessary infrastructure / equipment / skill sets in-house?

- PD contractors using state-of-the-art technologies

- Access to assets and technologies, lower investment

- Decreased time between drug development milestones

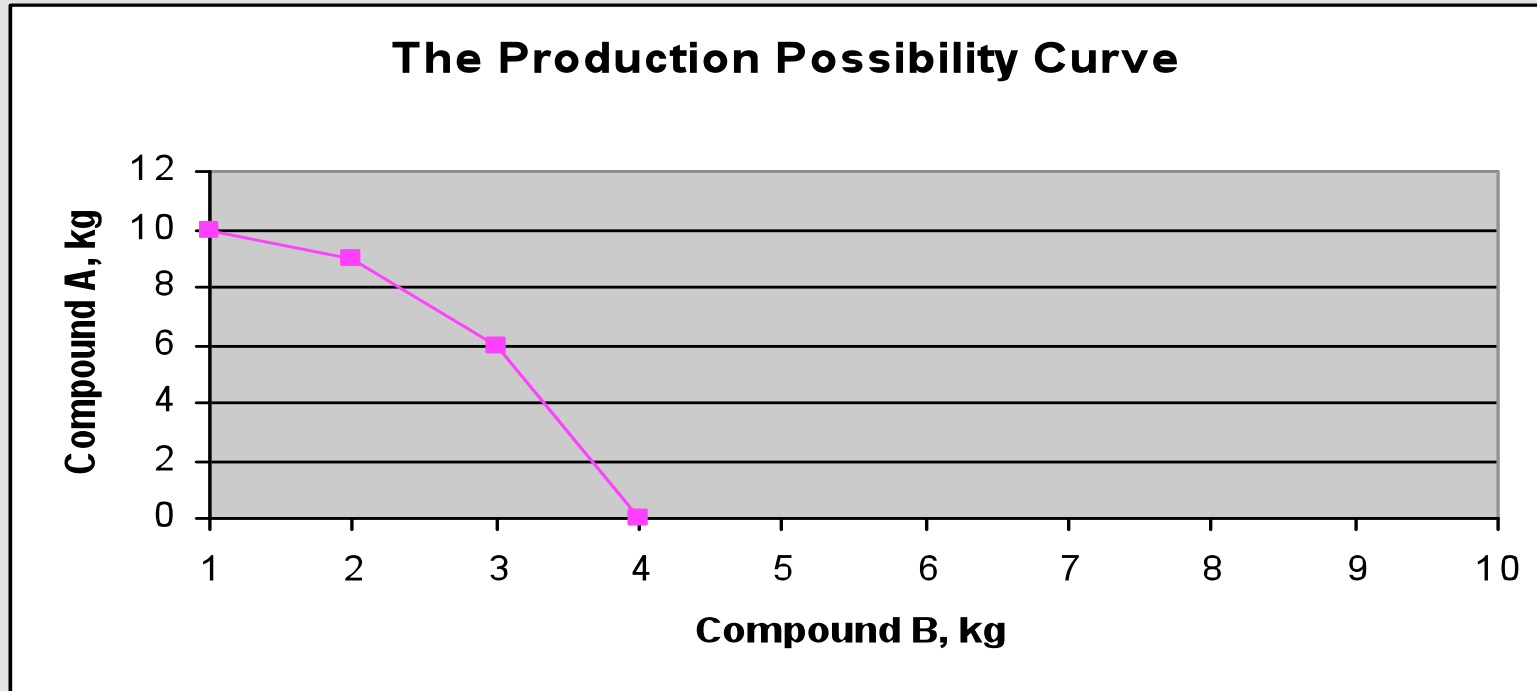
2. Economic Efficiency

Maximum Economic Efficiency embodies both allocative and production efficiency

- **Allocative Efficiency:** allocation of resources to the products most desired
- **Production Efficiency:** adoption of least costly production techniques

Maximum economic efficiency = maximum output gained

2. Opportunity Cost



Allows company to direct resources to core competencies

Maximum efficiency is key to a healthy ROI

3. Technical & Operational Capabilities

- Range and depth of core and complementary services
 - Technical ability
 - Experience
 - Reputation
 - Assets (Staff / Equipment)
 - Scope
 - Scale

Ability to design a scalable manufacturing process suitable for commercial production at an early stage

4. Strategic Fit and Risk Mitigation

- Leverage PD contractor's expertise
 - Avoid mistakes
 - Reduced development times
- Leverage PD contractor's know-how and IP
 - Unique proprietary position
- Adoption of risk management strategies

Allows implementation of high return strategies

Why Outsource within Australia?

- ***NCRIS***
Up to 75% discount vouchers for eligible researchers
- ***R&D Tax Credits***
45% refundable tax credits for companies with turnover <\$20m
40% non-refundable tax credits for companies with revenues >\$20m
- ***Venture Funding Available***
\$83m for follow-on funding for venture capital
- ***CTN Scheme***
Fast, simple CTN scheme, when compared to EMEA and FDA
- ***Locality***
Close to CTN trial sites, work in real time
Reinvesting in Australian biotech sector

protEcol[®] Services

microbial expression experts



- **Process development & manufacture of recombinant proteins in *E. coli* for global preclinical, clinical & commercial supply**
- **Purpose built GMP facility in Adelaide, licensed by TGA**
- **Operates in accordance with ICHQ7**

NCRIS: Provides discounted access to facility

protEcol[®] Services

microbial expression experts

CASE STUDY

- Avipep - Australian company
- Requiring GMP material for international clinical trial

Without NCRIS: stalled or taken off shore

NCRIS

- Able to manufacture in Australia
 - Real time operations
- Accessed discount vouchers
 - Significant reduction in cost
- Kept business within Australia
 - Sustainability and growth of local biotechnology industry

protEcol[®] Services



Process Development & Manufacture of Recombinant Proteins and Peptides

P: +61 8 8234 2660

W: <http://one2one.hospira.com/protocolservices.aspx>

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through the right people and the right products

