Attracting Investments and Generating Revenue – CSL Case Study

Bill Cracknell – January 2013
ABOUT CSL
Where it all began – Melbourne, 1916

CSL was formed as a government department in 1916 to serve & protect Australia. Now we are a global company but remain proudly Australian.
# The three businesses of CSL

<table>
<thead>
<tr>
<th>CSL Behring</th>
<th>bioCSL</th>
<th>Research &amp; Development</th>
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<tbody>
<tr>
<td>Global</td>
<td>Australia, USA &amp; NZ</td>
<td>Global</td>
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<tr>
<td>9,000+ employees</td>
<td>1,000+ employees</td>
<td>800+ employees (Aus &amp; global)</td>
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**CSL Behring**

Develops, manufactures & markets plasma therapies for the treatment of:
- Coagulation disorders
- Immunological disorders
- Pulmonary therapies
- Would healing therapies
- Critical Care therapies

Owns & operates one of the world’s largest plasma collection networks. manufactures & distributes plasma therapies for Australia, New Zealand and regional Governments.

**bioCSL**

Manufactures & markets seasonal & pandemic influenza vaccine globally.

Manufactures products of National Significance for Australia.

In-licences and distributes human vaccines & pharmaceutical products for Australia & New Zealand.

Manufactures & markets in vitro diagnostic products for immunohaematology and snake venom detection.

Provides specialist cold chain logistics & distribution services.

**Research & Development**

Develops new & improved protein-based therapies for treating serious illnesses & products that align with technical and commercial capabilities

- Haemophilia
- Immunoglobulins
- Speciality Plasma Products
- Breakthrough medicines
CSL Influenza Vaccine History

- First produced a ‘vaccine’ to combat 1918 ‘Spanish Flu’ pandemic, though at this time influenza was regarded as a bacterial disease!
- Been producing flu vaccine in eggs since mid-1940s
- Current influenza vaccine product first licensed in 1968
- In excess of 200 million doses of vaccine distributed globally in the last 5 years
- Currently, sole manufacturer of flu vaccine in Southern Hemisphere
Current Influenza Vaccine Supply

Registration in 28 countries, but sales in 11 only
Current Influenza Supply

- Current spread of sales:
  - US 39%
  - EU 47%
  - ANZ 13%
  - ROW 1%
INFLUENZA - AN INVESTMENT DILEMMA - WHY IS IT LIKE EASTER EGGS?
Seasonal Production

<table>
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<tr>
<th>December</th>
<th>January</th>
<th>February</th>
<th>March</th>
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<td>June</td>
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<td>August</td>
<td>September</td>
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<td>November</td>
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- Add to this:
  - Late strain selection
  - Virus growth/yield issues
  - Availability of Test Reagents
  - Think of a problem!!
CSL TECHNOLOGY TRANSFER MODEL
CSL Technology Transfer Model

- Three-stranded cord:
  - Science/Compliance
  - Public Health
  - Economics

- CSL model - establish Economics in Parallel with Science/Compliance
  - Step-wise approach
  - Ensure SUSTAINABILITY of transferred technology
  - Public Health benefit is derived from sustainable vaccine supply
  - Smaller initial quantities can be accommodated whilst market is established – buffer from the ‘flu phenomena’.
Technology Transfer Model

- Transfer is more about ‘Know-How’ than Technology
- Transfer:
  - Multi-Stage Process
  - CSL Assistance at each stage
  - Quality Systems advice at ALL stages
Indicative Technology Transfer Stages

**STAGE 1**
- Advice – equipment selection/cGMP compliance for fill and finish facilities
- Qualification of line / assay validation
- Product Registration Advice/Assistance
- Supply seasonal bulk for filling – grow & expand market/s
- Supply small volumes of finished product to establish market
- QC/Technical Assistance/Establishment of Assay Techniques

**STAGE 2**

**STAGE 3**
Donor Organisation Issues

- **Opportunity Cost?**
  - Donor Organisation must involve best human resources available – at possible detriment to own activities
  - Recipient Organisation may not be in a position to fund activities
  - No short-term financial return
  - Requires innovative third-party involvement to assist
Thank You for your Attention!