Mandate of OBP

South African State Owned Company (SOC)

The mandate of OBP is to prevent and control animal diseases that impact food security, human health and livelihoods.

Modest profits to ensure sustainability
RVF threat to animal, human and food security - South Africa
Onderstepoort RVF vaccines

- **RVF inactivated**
  - South Africa (G 1349; Act 36/1947)
  - Namibia (NSR 0966)
  - Tanzania
- **RVF Smithburn**
  - South Africa (G 0119; Act 36/1947)
  - Namibia (NSR 0580)
  - Tanzania
- **RVF Clone 13**
  - South Africa (G 3876; Act 36/1947)
  - Namibia (NSR 1516)
RVF vaccines currently in use
South Africa - timelines

1971
Live RVF (Smithburn)

1974
RVF Epidemic

1977
Inactivated RVF

1999
1st POC trials with RVF Clone 13

2006
Clinical trial work start RVF Clone 13

2008
RVF Epidemic
FS 2008
KZN 2009
NCape 2010
ECape 2011

2009
RVF Epidemic

2008
RVF Clone 13 dossier to Act 36

2010
RVF Clone 13 launch

2011
RVF vaccines currently in use
Live attenuated RVF Smithburn vaccine

Live attenuated
(Smithburn strain) (1971)

- Mouse adapted partially attenuated Smithburn strain
- Relatively easy and safe to produce
- Relatively short lead time
- Immunogenic after single dose
- Long lasting immunity
- **BUT** annual vaccination in endemic areas is recommended

**Concerns:**
- May be teratogenic in pregnant animals
- Risk of reversion to virulence
- Not advisable for use in an outbreak
Inactivated RVF vaccine

Inactivated vaccine (virulent field strain) (1977)

- Wild-type, virulent virus
- Inactivated adjuvanted vaccine
- Long lead time
- High antigen payload required
- Safe in pregnant animals
- Can be used in outbreak
- Booster dose and more frequent vaccination required to maintain adequate level of immunity

Concerns:
- Occupational risk in manufacturing
- Special, isolated production facility needed – occupational hazard/risk
RFV C13

RFV Clone 3
(avitulent RVF, 74HB59 strain)

- Highly attenuated naturally avirulent
- Potential DIVA vaccine: deletion (549 nucleotides) within the NSs segment
- Safe for use in early pregnancy
- Safe for use in sheep/goats and cattle
- Induces a good protective antibody response
- Vaccine production is safe and cost-effective
- Comparable lead time to live vaccine

Concerns:
- Stability problems
- Cold storage chain maintenance
- Short shelf life
Distribution of RVF – Target markets?

Countries with endemic disease and substantial outbreaks of RVF:
Gambia, Senegal, Mauritania, Namibia, South Africa, Mozambique, Zimbabwe, Zambia, Kenya, Sudan, Egypt, Madagascar, Saudi Arabia, Yemen

Countries known to have some cases, periodic isolation of virus, or serologic evidence of RVF:
Botswana, Angola, Democratic Republic of the Congo, Congo, Gabon, Cameroon, Nigeria, Central African Republic, Chad, Niger, Burkina Faso, Mali, Guinea, Tanzania, Malawi, Uganda, Ethiopia, Somalia

Source: OIE
# Vaccination strategy conundrum

<table>
<thead>
<tr>
<th>Rift Valley Fever</th>
<th>Country Examples</th>
<th>Control Strategy</th>
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<tbody>
<tr>
<td>Endemic with regular outbreaks</td>
<td>Kenya, Tanzania, Egypt, Senegal, Mali</td>
<td>Continuous vaccination/yearly vaccination</td>
</tr>
<tr>
<td>Endemic with sporadic/re-occurring outbreaks</td>
<td>South Africa, Saudi Arabia</td>
<td>Continuous/yearly vaccination</td>
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<tr>
<td>Free-High risk</td>
<td>Middle East, North Africa</td>
<td>(Active) surveillance</td>
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<tr>
<td>Free-Low risk</td>
<td>Europe, Americas</td>
<td>Surveillance, talks of vaccine banks</td>
</tr>
</tbody>
</table>

Source: OIE, 2012
RVF 5 year usage OBP vaccines

African countries

Units sold

Boysana
Djibouti
Zambia
Kenya
Korea
Malawi
Namibia
Zimbabwe
Somalia
Sudan
Tanzania
Switzerland
Other countries

Other countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Units sold</th>
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<tbody>
<tr>
<td>Saudi Arabia</td>
<td>58,700</td>
</tr>
<tr>
<td>FOA of UN</td>
<td>10,700</td>
</tr>
<tr>
<td>Netherlands</td>
<td>4,000</td>
</tr>
<tr>
<td>France</td>
<td>3,000</td>
</tr>
<tr>
<td>United Arab Emirates</td>
<td>30,700</td>
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</tbody>
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RFV 5 year usage
Onderstepoort RVF vaccines

Situation in South Africa
- During outbreaks a huge demand for vaccines (1973/74; 1994; 2008/09; 2010)
- In between outbreaks – vaccine stock often destroyed due to expiry

Average 300 000

OBP RVF vaccine doses sold in South Africa between 2002 and 2010.

22 million
Product development roadmap at OBP

1. Discovery
2. POC
3. Pre-Clinical Trial
4. Clinical Trial
5. Dossier submission
RFV Clone 13 Pipeline and continuous vaccination strategy stimulation

- **RVF Clone 13 vaccine stability:**
  - Stable for 9 months as a freeze dried product at 4 degree C
  - Testing of different stabilizers and temperatures

- **RVF Clone 13 multivalent:**
  - RVF/Lumpy Skin Disease vaccine combination
Thank You